

| Basic information | |
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| <p>2002/0051(COD)</p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p> | Procedure completed |
| <p>Developing countries, poverty diseases: combating HIV/AIDS, malaria and tuberculosis</p> <p>Repealed by 2004/0220(COD)</p> <p>Subject</p> <p>4.20.01 Medicine, diseases 6.40.12 Relations with developing countries in general</p> | |

| Key players | | | | |
|---------------------|---|------------------------------|---|------------------|
| European Parliament | Committee responsible | | Rapporteur | Appointed |
| | DEVE Development and Cooperation | | WIJKMAN Anders (PPE-DE) | 18/04/2002 |
| | Committee for opinion | | Rapporteur for opinion | Appointed |
| | BUDG Budgets | | GILL Neena (PSE) | 19/03/2002 |
| | CONT Budgetary Control | | The committee decided not to give an opinion. | |
| | ENVI Environment, Public Health, Consumer Policy | | ROD Didier (V/ALE) | 27/03/2002 |
| | Council of the European Union | Council configuration | | Meetings |
| General Affairs | | 2509 | 2003-05-19 | |
| General Affairs | | 2518 | 2003-06-16 | |
| Development | | 2429 | 2002-05-30 | |
| European Commission | Commission DG | | Commissioner | |
| | Development | | | |

| Key events | | | |
|------------|-------|-----------|---------|
| Date | Event | Reference | Summary |

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|------------|---|--|---------|
| 04/03/2002 | Legislative proposal published | COM(2002)0109  | Summary |
| 11/03/2002 | Committee referral announced in Parliament, 1st reading | | |
| 30/05/2002 | Resolution/conclusions adopted by Council | | |
| 11/11/2002 | Vote in committee, 1st reading | | Summary |
| 11/11/2002 | Committee report tabled for plenary, 1st reading | A5-0394/2002 | |
| 30/01/2003 | Decision by Parliament, 1st reading | T5-0031/2003 | Summary |
| 30/01/2003 | Debate in Parliament |  | |
| 03/04/2003 | Modified legislative proposal published | COM(2003)0167  | Summary |
| 16/06/2003 | Act adopted by Council after Parliament's 1st reading | | |
| 15/07/2003 | Final act signed | | |
| 15/07/2003 | End of procedure in Parliament | | |
| 06/09/2003 | Final act published in Official Journal | | |

| Technical information | |
|----------------------------|--|
| Procedure reference | 2002/0051(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Legislation |
| Legislative instrument | Regulation |
| Amendments and repeals | Repealed by 2004/0220(COD) |
| Legal basis | EC Treaty (after Amsterdam) EC 179-p1 |
| Stage reached in procedure | Procedure completed |

| Documentation gateway | | | | |
|---|--|---|------------|---------|
| European Parliament | | | | |
| Document type | Committee | Reference | Date | Summary |
| Committee report tabled for plenary, 1st reading/single reading | | A5-0394/2002 | 11/11/2002 | |
| Text adopted by Parliament, 1st reading/single reading | | T5-0031/2003 OJ C 039 13.02.2004, p. 0016-0058 E | 30/01/2003 | Summary |
| European Commission | | | | |
| Document type | Reference | Date | Summary | |
| Legislative proposal | COM(2002)0109  OJ C 151 25.06.2002, p. 0202 E | 04/03/2002 | Summary | |
| | COM(2003)0167 | | | |

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| Modified legislative proposal |  | 03/04/2003 | Summary |
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| Additional information | | |
|------------------------|----------|------|
| Source | Document | Date |
| European Commission | EUR-Lex | |

| Final act | |
|---|-------------------------|
| Regulation 2003/1568 OJ L 224 06.09.2003, p. 0007-0012 | Summary |

Developing countries, poverty diseases: combating HIV/AIDS, malaria and tuberculosis

2002/0051(COD) - 03/04/2003 - Modified legislative proposal

The European Commission accepts in full all amendments put forward by Parliament during its first reading of the proposal. This includes the proposed increase in the budget allocated to the programme from EUR 300 million for the period 2003-2006 to EUR 351 million for the same period.

Developing countries, poverty diseases: combating HIV/AIDS, malaria and tuberculosis

2002/0051(COD) - 04/03/2002 - Legislative proposal

PURPOSE : to propose a Regulation to implement the Action Programme for HIV/AIDS, malaria, and tuberculosis. **CONTENT** : this Regulation repeals Council Regulation 97/550/EC. The purpose of activities carried out under the Regulation will be to: - optimise the impact of existing interventions; - increase the affordability of key pharmaceuticals; - increase research and development, including vaccines, microbicides and innovative treatments. Community financial support will be given to specific projects designed to further these objectives. Such projects include those which, inter alia: - improve pharmaceutical policies and practice, and help developing countries to develop local production of off-patent and/or licensed key pharmaceuticals; - promote global tiered pricing for key pharmaceuticals in developing countries; - analyse the effect of factors, such as the level of net import price, tariffs, taxes, and importation, distribution and local registration fees, on consumer process of medical goods in developing countries; - provide 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 by the Doha Declaration. Community financial support may take the form of: - financial assistance; - technical assistance, training or other services; - supplies, such as medical supplies and commodities, and works; - audits and evaluation and monitoring missions. Priority will be given to enhancing national capacity with a view to long-term viability. Financing will take the form of grants. Contractors from all the developing countries as well as Member States will be allowed to bid for the procurement of services and products. This may be extended, in exceptional cases, to other third countries.

Developing countries, poverty diseases: combating HIV/AIDS, malaria and tuberculosis

2002/0051(COD) - 30/01/2003 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Anders WIJKMAN (EPP-ED, Sweden) and made some amendments to the Commission's proposal. (Please refer to the document dated 11/11/02.) The financial framework from 2003 to 2006 was set at EUR 351 million. Parliament added a number of recitals expanding on the amendments made to the articles. It emphasised that poverty diseases are among the problems that require a systematic, coordinated response by the international community. Interventions in this area are in everyone's interest and therefore should not be viewed as a question of development aid alone. The Doha declaration on TRIPS and Public Health affirmed that the TRIPS Agreement " can and should be implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all." It reaffirmed the right of WTO members to use to the full provisions in the TRIPS Agreement, which provide flexibility for this purpose. Inadequate public policy has compounded the failure of the market to generate research and development for neglected diseases. In 2000, only 10% of R&D concerned diseases that are responsible for 90 of diseases in the world. Increased public funding is needed, including supporting the research and

development of specific global public goods and methods of prevention and treatment and the introduction of appropriate incentives for the private sector to invest accordingly.

Developing countries, poverty diseases: combating HIV/AIDS, malaria and tuberculosis

2002/0051(COD) - 15/07/2003 - Final act

PURPOSE : to put in place a Community instrument to fight poverty diseases (HIV/AIDS, tuberculosis and malaria) in developing countries.

LEGISLATIVE ACT : Regulation 1568/2003/EC of the European Parliament and of the Council on aid to fight poverty diseases (HIV/AIDS, tuberculosis and malaria) in developing countries. **CONTENT** : this Regulation shall replace Council Regulation 550/97/EC (HIV/AIDS- related operations in developing countries) and shall provide for a more comprehensive package targeting interventions related to development co-operation, trade relations and research for new pharmaceutical products, for the three major communicable diseases: HIV/AIDS, malaria and tuberculosis. The burden of preventable communicable diseases such as HIV/AIDS, malaria and tuberculosis, in developing countries is still very high, resulting in profound human and economic costs. The European Community Programme for Action on accelerated action targeting three major communicable diseases in the context of poverty reduction presents an ambitious policy framework for action which needs substantial additional financial resources to achieve its goals. Therefore, the Community shall implement this Programme targeting the three major communicable diseases. 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. In the allocation of such funding and expertise, priority shall be given to: - the poorest and least developed countries and the most disadvantaged sections of the population within developing countries; - action that complements and reinforces both the policies and capacities of developing countries and the assistance provided through other instruments of development cooperation. The purpose of the activities carried out under this Regulation shall be to: - optimise the impact of existing interventions, services and commodities aimed at preventing and fighting the major communicable diseases affecting the poorest populations; - increase the affordability of key pharmaceuticals and diagnostics for the three diseases; - increase research and development, including vaccines, microbicides and innovative treatments. Community financial support shall be given to specific projects designed to achieve the purposes described in Article 2 and, in particular, to those which aim to: - provide the necessary technical, scientific and normative input in order to prioritise health interventions within the total development cooperation budget and improve health outcomes relating to the three major communicable diseases, keeping a balanced approach between prevention, treatment and care, with prevention as a key priority, acknowledging that its effectiveness is increased when linked with treatment and care; recognition has to be given to the fact that important measures have to be looked for through a multi-sectoral approach, including targeting behavioural patterns as well as factors such as clean water and sanitation, land-use planning, nutrition and gender mainstreaming; - 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; - improve understanding of effects of the poverty diseases on social and economic development, as well as the impact of strategies aimed at mitigating the negative socioeconomic effects connected with the diseases; - improve pharmaceutical policies and practice, and help developing countries, at regional or national level, to develop high-quality local production of key preventive and therapeutic pharmaceuticals consistent with the Doha Declaration on the Agreement on trade-related aspects of intellectual property (TRIPs) and Public Health; - promote a tiered pricing mechanism for key pharmaceuticals for developing countries that will guarantee the lowest possible prices; - analyse the effects of factors such as the level of net import price, tariffs, taxes, and importation, distribution and local registration fees on consumer prices of medical goods in developing countries; - provide, where appropriate, technical assistance to developing countries to help them address public health issues in accordance with the provisions of the TRIPs Agreement as clarified in the Doha Declaration on the TRIPs Agreement and Public Health, so as to enable the developing countries to protect public health and promote access to medicines for all; - encourage public investment and develop an incentive package to encourage more private investment in Research and Development for new treatments, particularly vaccines and microbicides, diagnostics, and fixed-dose combinations designed to fight the major communicable diseases in developing countries; - support team-based clinical, epidemiological, operational and social studies, so as to enable health-related research to be conducted on a sounder basis; where appropriate, teams shall be encouraged also to include personnel from the developing countries as a way of contributing to the training of such personnel; - encourage capacity building in developing countries, to enable them to coordinate, host and conduct large-scale population trials and to complete all stages of the research and development process; - support global initiatives targeting the major communicable diseases in the context of poverty reduction, including the Global Fund to fight HIV/AIDS, tuberculosis and malaria which came into operation on 29 January 2002; - support initiatives which enable the quality of pharmaceuticals to be supervised and monitored. Community financing under this Regulation shall take the form of grants. In the context of certain operations, financial assistance shall be granted in coordination with the new instruments for product research and development on poverty-related communicable diseases implemented under the Community Framework Programme of Research and Development 2002-2006. The contribution to the Global Fund to fight HIV/AIDS, tuberculosis and malaria shall be made by means of a financing agreement to be concluded between the Commission and the Trustee of the Global Fund. In the context of other operations, efforts shall be made to exploit the synergies with policies and programming in the area of sexual and reproductive health, in particular for HIV/AIDS interventions. The partners eligible for financial assistance under this Regulation include the classic cooperation partners such as administrative authorities and agencies at national, regional and local government level; local authorities and other decentralised bodies, etc. The financial framework for the implementation of this Regulation for the period from 2003 to 2006 is set at EUR 351 million. Decisions concerning operations for which financing under this Regulation exceeds EUR 5 million and any changes to these operations that entail a cost overrun of more than 20 % of the amount initially fixed for the operation concerned shall be adopted. For decisions and changes to these operations amounting to EUR 5 million or less, the Commission shall inform the Member States. After each budget year, the Commission shall submit, in its annual report to the European Parliament and to the Council on Community development policy, information on the guidelines for its annual indicative strategic programme and on the operations financed in the course of that year. **ENTRY INTO FORCE** : 9 September 2003. This Regulation shall apply until 31 December 2006.