Basic information

2002/0211(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Decision	Procedure completed
Combating Aids, malaria and tuberculosis: research partnership Europe /developing countries **Subject** 4.20.01 Medicine, diseases 6.40.12 Relations with developing countries in general	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ITRE Industry, External Trade, Research, Energy	CAUDRON Gérard (GUE /NGL)	08/10/2002

Committee for opinion	Rapporteur for opinion	Appointed
BUDG Budgets	HUDGHTON Ian (V/ALE)	08/10/2002
ENVI Environment, Public Health, Consumer Policy	The committee decided not to give an opinion.	
DEVE Development and Cooperation (Associated committee)	SANDBÆK Ulla Margrethe (EDD)	02/10/2002
FEMM Women's Rights and Equal Opportunities	EVANS Jill (V/ALE)	05/11/2002

Council of the European Union

Council configuration	Meetings	Date
Competitiveness (Internal Market, Industry, Research and Space)	2505	2003-05-13
Competitiveness (Internal Market, Industry, Research and Space)	2467	2002-11-26

European Commission

Commission DG	Commissioner
Research and Innovation	

Key events

Date	Event	Reference	Summary
28/08/2002	Legislative proposal published	COM(2002)0474	Summary
02/09/2002	Committee referral announced in Parliament, 1st reading		
26/11/2002	Debate in Council		Summary
23/01/2003	Vote in committee, 1st reading		Summary
23/01/2003	Committee report tabled for plenary, 1st reading	A5-0027/2003	
27/03/2003	Decision by Parliament, 1st reading	T5-0123/2003	Summary
27/03/2003	Debate in Parliament		
29/04/2003	Modified legislative proposal published	COM(2003)0223	Summary
13/05/2003	Act adopted by Council after Parliament's 1st reading		
16/06/2003	Final act signed		
16/06/2003	End of procedure in Parliament		
08/07/2003	Final act published in Official Journal		

Technical information

Procedure reference	2002/0211(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Decision
Legal basis	EC Treaty (after Amsterdam) EC 169 EC Treaty (after Amsterdam) EC 172 Rules of Procedure EP 57_o
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		A5-0027/2003	23/01/2003	
Text adopted by Parliament, 1st reading/single reading		T5-0123/2003 OJ C 062 11.03.2004, p. 0019-0150 E	27/03/2003	Summary

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2002)0474	28/08/2002	Summary

Modified legislative proposal	COM(2003)0223	29/04/2003	Summary
Follow-up document	COM(2008)0688	30/10/2008	Summary
Follow-up document	SEC(2008)2723	30/10/2008	Summary
Follow-up document	SEC(2008)2724	30/10/2008	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0039/2003 OJ C 133 06.06.2003, p. 0093-0096	26/03/2003	
EESC	Economic and Social Committee: opinion, report	CES0414/2003	26/03/2003	

Additional information

Source	Document	Date
European Commission	EUR-Lex	

Final act

Decision 2003/1209
OJ L 169 08.07.2003, p. 0001-0005 Summary

Combating Aids, malaria and tuberculosis: research partnership Europe /developing countries

2002/0211(COD) - 26/11/2002

The Council held an exchange of views on the proposal for a Decision of the European Parliament and the Council on Community participation in a research and development programme aimed at developing clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries. Following the debate, the Presidency drew the following conclusions: The Council confirmed its intention to pursue this proposal as a pilot programme for the use of Article 169, it being acknowledged that further detailed discussions with the European Parliament will take place. In this context, Ministers: - underlined the importance of ensuring the commitment of financial and human resources at the national level, including, as appropriate, those of third countries, to carrying out these activities; - stressed the importance of associating very closely the developing countries with all aspects of the programme, including in the decision making process, and reinforcing current collaboration in this area as well as ensuring the establishment of the necessary modalities for effective coordination between the different actors in this field. Recognising the pioneering nature of this proposal, Ministers stressed the need for an in-depth examination of all aspects of this initiative and how best to link this programme to other activities in the implementation of the Sixth Framework Programme and the creation of ERA. Ministers stressed the need for establishing the appropriate structure and effective management arrangements for carrying out the programme, bearing in mind the need to provide for a similar level of scientific excellence and protection of Community financial interests as in other instruments implementing the Sixth Framework Programme. As to the way forward, therefore: - the Permanent Representative Committee should continue the examination of this proposal in close cooperation with the European Parliament, with particular attention to the modalities of the Community participation in EDCTP and

also the question of liability of the participants; - the participating Member States should agree on the form of the legal entity and the common structure which will be responsible for the implementation and execution of the EDCTP activities, prior to the decision being taken by the European Parliament and the Council.

Combating Aids, malaria and tuberculosis: research partnership Europe /developing countries

2002/0211(COD) - 28/08/2002 - Legislative proposal

PURPOSE : to propose a new partnership between Europe and the developing countries for the development of new medecines and new vaccines agasint HIV/AIDS, malaria and tuberculosis. CONTENT : the European Commission has proposed to support a long-term partnership between Europe and developing countries by providing EUR 200 million for the development of new medicines and vaccines against HIV/AIDS, malaria and tuberculosis. This European and Developing Countries Clinical Trials Partnership (EDCTP) brings together EU Member States plus Norway, developing countries and industry in a joint effort to combat poverty-linked diseases. To adequately furnish the EDCTP programme with the necessary financial means, the European Commission has now proposed to contribute EUR 200 million of Community funds towards the EUR 600 million required for the total financial volume of the programme. Further EUR 200 million worth of activities stem from participating countries' national clinical research programmes that are brought together under a common objective. The remaining EUR 200 million will be acquired from other donors and industry. This initiative by the EU and participating European countries will allow for the rapid launching of a first set of urgent measures, once European Parliament and Council have given their green light. The vicious circle of disease and poverty causes a fundamental public health and economic crisis in developing countries, particularly in Sub-Saharan Africa. HIV/AIDS, malaria and tuberculosis (TB) alone account for more than five million deaths every year, 95% of these in the developing world. To respond to this emergency, the Commission launched already in 2001 its Programme for Action, based on three pillars: impact, affordability and research & development. The Programme for Action aims at combating HIV /AIDS, malaria and tuberculosis with the emphasis on poverty reduction. The EDCTP is a response for more and better research and development activities to fight the three diseases. To be successful, such a partnership initiative must evolve under the guidance of developing countries as the drivers of the real needs. Therefore, the EDCTP initiative has ensured that African clinicians and health system representatives took already part in this initiative at its very early stages, enabling them to assume a leading role in its further development. Similarly, to encompass the essential expertise that only industry can provide with respect to the clinical development of new drugs and vaccines. In practical terms, the EDCTP programme foresees: - central European and African management facilities; - measures for improved networking of European clinical research programmes and for global advocacy; - support for clinical research capacities in developing countries; - a training scheme for local researchers and clinicians that will strengthen the locally available human resources to guarantee the long-term sustainability of the EDCTP programme; - and, as its core mandate, support for prioritised clinical trials of new drugs and vaccine candidates that urgently await clinical testing. The present initiative, in line with the idea of a EuropeanResearch Area, is perfectly integrated within the activities of the 6th Framework Programme and represents the first attempt of a joined research programme between the European Union, Member States and associated countries. EU Member States and Norway will invest at national level more than EUR 1 billion for the years 2002-2007 in biomedical research to develop new clinical means to cure or prevent HIV/AIDS, malaria and tuberculosis.

Combating Aids, malaria and tuberculosis: research partnership Europe /developing countries

2002/0211(COD) - 29/04/2003 - Modified legislative proposal

The Commission states that the Parliament's changes are in line with the approach proposed by the Commission. They provide useful clarification for implementing the programme. The Commission can therefore accept all of them.

Combating Aids, malaria and tuberculosis: research partnership Europe /developing countries

2002/0211(COD) - 16/06/2003 - Final act

PURPOSE : to propose a new partnership between Europe and the developing countries for the development of new medicines and new vaccines against HIV/AIDS, malaria and tuberculosis. COMMUNITY MEASURE : Decision 1209/2003/EC of the European Parliament and of the Council on Community participation in a research and development programme aimed at developing new clinical interventions to combat HIV/AIDS, malaria and tuberculosis through a long-term partnership between Europe and developing countries, undertaken by several Member States. CONTENT : This Decision provides for a Community contribution to EDCTP Programme, which has been set up by certain participating Member States and Norway together with developing countries, in order to ensure a coherent programme for research to combat HIV/AIDS, malaria and TB. The total cost of the Programme is estimated at EUR 600 million over a five-year period. The objective of the EDCTP Programme is to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in the developing countries, particularly in sub-Saharan Africa, and to improve generally the quality of research in relation to these diseases. The EDCTP Programme has been drawn up with a view to stepping up cooperation and the networking of European national programmes, accelerating clinical trials of new products, in particular drugs and vaccines, in the developing countries, helping to develop and strengthen capacities in the developing countries, including the promotion of technology transfer where appropriate and encouraging the participation of the private sector. The overall value of the participation of the participating Member States is estimated at EUR 200 million. Activities linked to obtaining additional funds, whether public or private, estimated at EUR 200 million, are provided for in the implementation of the EDCTP Programme. This Decision provides that the Community will pay a financial contribution to the common structure

amounting to a maximum of EUR 200 million for the duration of the sixth framework programme established by Decision 1513/2002/EC. The Community financial contribution will be paid from the budget appropriation allocated to the priority theme 'Life sciences, genomics and biotechnology for health' of the specific programme of the sixth framework programme entitled 'Integrating and strengthening the European Research Area (2002 to 2006)'. The Community financial participation is conditional upon several specified matters, including the setting up by participating Member States of a common structure for receiving and allocating the Community financial contribution. The other conditions include: - the establishment of the governance model for the EDCTP Programme involving a Partnership Board and in conformity with the guidelines set out in Annex II; - ensuring a high level of involvement of developing countries; - ensuring a high level of scientific excellence and observance of ethical principles in accordance with the general principles of the sixth framework programme; and - formulation of the provisions relating to intellectual property rights in such a way that they also aim at ensuring that the people of developing countries have easy and affordable access to the research results produced by activities under the EDCTPProgramme and to the products directly deriving from its results. The Commission must conduct an evaluation of the EDCTP Programme at the end of five years.

Combating Aids, malaria and tuberculosis: research partnership Europe /developing countries

2002/0211(COD) - 27/03/2003 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Gerard CAUDRON (EUL/NGL, France) made several amendments to the Commission's proposal. In order to fight HIV/AIDS in developing countries, participating Member States, together with Norway, are setting up a research and development programme entitled "The European and Developing Countries Clinical Trials Partnership" (EDCTP Programme). EUR 600 million is to be seen as a target figure, with the participating Member States contributing up to EUR 200 million. The programme will be administered by a partnership board, which will ensure a balanced participation of experts from the participating European States and from the developing countries involved in the programme. It will define the strategy of the programme to be approved by the common structure. The latter will have legal personality and be the recipient of the Community contribution. The arrangements for the financial participation of the Community and the rules relating to financial liability and to intellectual property rights will be adopted jointly by the Commission and the common structure, in accordance with the financial regulation applicable to the Community budget. Parliament insisted on a high level of participation of developing countries. Provisions relating to intellectual property rights aim to ensure that the people of developing countries have easy and affordable access to the research results produced by activities under the EDCTP Programme and to the products directly deriving from its results. The Commission must conduct an evaluation of the EDCTP Programme at the end of five years.

Combating Aids, malaria and tuberculosis: research partnership Europe /developing countries

2002/0211(COD) - 30/10/2008 - Follow-up document

This report outlines the state of progress on the European and Developing Countries Clinical Trials Partnership (the EDCTP Programme) which was established, in 2003, by Decision of the European Parliament and of the Council by 14 Member States (all the then Member States except Finland) and Norway (Switzerland joined the EDCTP in 2005). The objectives were to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in the developing countries, particularly in sub-Saharan Africa, and to improve the quality of research in relation to these diseases. Created under the umbrella of the Article 169 of the Treaty, the EDCTP Programme aims at coordinating and jointly implementing activities at Member State level.

EDCTP is managed through a General Assembly where Member States are represented, a Secretariat under the Executive Director, and a High Representative. Advisory bodies include the Partnership Board (the scientific advisory board), the Developing Countries Coordinating Committee, and the European Network of National Programmes.

The Community has made a contribution to the EDCTP through a €200 million financial contribution under the 6th Framework Programme for Research and Technological Development (2002-2006) – FP6. The participating Member States provide 50% co-funding, both in cash and in kind, increasing the total EDCTP budget to €400 million. An additional €200 million funding from third parties is also envisaged.

The EDCTP Programme had an initial implementing phase (from 2003 to 2006) that was slower than initially foreseen. Over that period, budget spending was abnormally low, calls for proposals were cancelled and a 2004 report from the European Court of Auditors (PF-1828 (6046)) revealed several deficiencies. During the same period, the Secretariat was under four different Executive Directors, two of them being ad interim. As a consequence, in 2006 Commissioner Janez Potočnik requested a panel of high level experts to prepare an Independent External Review (IER) report on the European and Developing Countries Clinical Trials Partnership, the so called van Velzen report, which was published in July 2007.

This progress report, published as a Commission Staff Working Document, is intended to inform on the achievements and current status of the first five years of the EDCTP Programme, from 2003 to 2008, following the recommendations of the Van Velzen report.

The time that has elapsed since its publication in July 2007 has allowed the implementation of most of its recommendations to the EDCTP Secretariat, Member States and Commission.

Since 2007, the EDCTP Secretariat has **redefined its scientific strategy**, through stakeholders' meetings held on the different diseases and products, increased collaboration with Public-Private Partnerships, renewed calls for proposals and simplified the co-funding.

Participating Member States have created a General Assembly Steering Committee, renewed their commitment to the EDCTP, reinforced African participation in the General Assembly, and are more and more accepting of a single central EDCTP evaluation.

The Commission is joining efforts of its relevant services in relation to EDCTP, working on a **strategic research policy for Africa including EDCTP**, and setting pre-conditions for future Article 169 initiatives, such as the necessity to ensure the pre-existence of national programmes and commitment to funding.

On the **operational side**, from September 2003 to May 2008, the EDCTP Programme has launched 33 calls and financed about 145 projects. Among these, 32 are clinical trials; 55 are training (MSc, PhDs and post doctoral) awards; 11 are supporting network activities; 14 are capacity building in ethics; 16 are Senior Fellowships; one project on strengthening the regulatory framework in Africa through collaboration with WHO; and one for the establishment and maintenance of a clinical trials registry. The projects are based in 26 different countries in sub-Saharan Africa, involving 123 institutions, and practically all participating Member States.

In particular, in 2007, the EDCTP launched 11 new calls for a total of €180 million (including €90 million of co-funding expected from Member States). In May 2008, and as partial outcome of these calls, the EDCTP General Assembly approved the financing of 8 new projects on malaria treatment, malaria vaccine, malaria in pregnancy, and tuberculosis vaccine; 8 new projects on capacity building for African ethical committees; 3 trans-disease regional networks of excellence (East, Central and West Africa), and 6 senior fellowships, for a total of about €87 million, including 50% co-funding from MS. The remaining calls are under evaluation.

As a result of all these calls, EDCTP has committed from 2003 to December 2007 €76.2 million (from EC, MS and third party funding) in grants, including a call co-funded by the Bill and Melinda Gates Foundation on HIV vaccines. In 2008, the EDCTP expects to increase this figure to over € 279 million.

However, since most projects are 3-year contracts, and some of them are just starting, the total EDCTP expenditure on research grants has been so far of €15.7 million. Out of the total commitment, 63% is going to African researchers. In 2007, 88% of the EDCTP budget was devoted to grants.

Member States' co-funding has increased from less than €1 million in 2005, to €6 million in 2006, and up to €21 million in 2007. Data from January to April 2008 already show €67 million committed or pledged from Member States.

Third party contributions contributed or committed from different foundations, product development public private partnerships and industries accounts so far for €34.1 million.

In the almost five years since its creation, the EDCTP has achieved **several important landmarks**:

- enhanced coordination of research activities and demonstrable capacity building;
- African researchers have an equal opportunity to their northern colleagues to develop proposals and become Principal Investigators;
- the EDCTP is urging African countries to establish national research budgets and to further contribute to the establishment of an African Fund for Health Research;
- EDCTP funding gives African researchers more ownership, provides better fora for discussion and knowledge exchange;
- capacities and sites developed are fully owned by the institutions and countries, avoiding scientific colonization;
- grantees have developed new research sites by accessing funding from other sources;

EDCTP funding is instrumental in the approval of some major health policy changes, such as the development of HIV treatment for children.

Combating Aids, malaria and tuberculosis: research partnership Europe /developing countries

2002/0211(COD) - 30/10/2008 - Follow-up document

The European and Developing Countries Clinical Trials Partnership (EDCTP Programme) was established in September 2003 by Decision of the European Parliament and of the Council5,6 to accelerate the development of new clinical interventions to fight HIV/AIDS, malaria and tuberculosis in the developing countries, particularly in sub-Saharan Africa, and to improve generally the quality of research in relation to these diseases.

Created as the first application ever of Article 169 of the Treaty, the EDCTP Programme aims at coordinating and jointly implementing activities run by the Member States in partnership with developing countries.

This Communication follows a recommendation in the Independent External Review (IER) report, also known as the Van Velzen report, that the Commission should inform the Council and the European Parliament about the current status of the EDCTP Programme, in advance of the 2008 evaluation (required by the original EDCTP Decision) due at the end of the first five years of the EDCTP.

The main conclusions are as follows:

The main challenges of the Programme: for the first time, 14 European Member States, together with Norway and Switzerland, are building a new structure to coordinate their clinical research activities on HIV/AIDS, malaria and tuberculosis in sub-Saharan Africa. The research financed will have a direct impact on the hardest-hit populations, in terms of **new drugs, vaccines** and public health interventions.

To recall, the main objectives of the programme were to:

1) Develop new interventions and products against poverty-related diseases. The fight against HIV/AIDS, malaria and tuberculosis needs both prophylactic (vaccines and microbicides) and therapeutic (drugs) tools to prevent infection and control disease progression.

2) Build sustainable public health and research capacity in Africa, so local populations can better control the pandemic. The coordination of development aid policy and research policy should aim at a better implementation of these separate policies into a long term strategy against the three diseases.

3) Coordinate European Member States' research policies. While the research activities of some European Union Member States in Africa have been remarkable, they could profit from better collaboration and coordination. Coordinating European national research programmes and policies on poverty-related diseases for Africa in line with Article 169 of the Treaty will increase the impact of European interventions against these diseases.

As part of the European contribution to the UN's Millennium Development Goals, the EDCTP is an important instrument in the fight against HIV/AIDS, malaria and tuberculosis. Better vaccines and treatments would help dramatically reduce the incidence of such diseases, and research is essential to developing these tools. The special nature of EDCTP activities — financing capacity building and research activities in developing countries — calls for collaboration on the part of development aid and research agencies.

Main achievement and lessons to be experience gained: the Commission considers Article 169 to be a powerful, ambitious instrument for coordinating national programmes and building the European Research Area. Activities conducted under this Article have a longer than average implementation phase, but come with **greater potential** and are able to deliver results not achievable with other instruments. As such, they should be considered long-term activities.

In this context, the EDCTP has made its mark in a number of important ways, starting to fulfil the original objectives of the Programme: i) to encourage African countries to establish national research budgets and to further contribute to the establishment of an African Fund for Health Research; ii) to facilitate funding to give African researchers more ownership, and provide better fora for discussion and knowledge exchange; iii) to enable capacity and sites developed to be fully owned by the institutions and countries, avoiding 'scientific colonisation'; iv) that grantees have developed new research sites by accessing funding from other sources; v) the **development of HIV treatment in children**.

Despite some serious initial difficulties, the performance of the EDCTP Programme has improved in the last two years, with specific achievements in line with the original goals of the Programme and with the recommendations of the Van Velzen report. The remaining two years of the EDCTP contract until 2010 will be crucial to determining the extent of Member States' financial and political commitment and the Secretariat's capacity to negotiate and follow up research contracts.

As learnt from the EDCTP, two of the main pre-conditions for new Article 169 initiatives are pre-existing national research programmes and a full funding commitment, in advance, from Member States. From the outset, the EDCTP Programme was set up as a long-term initiative which could only achieve its goals of research capacity-building in Africa, halting disease progression and integrating European research in the long term. Nevertheless, progress in the medium term should be objective and measurable.

Follow-up: as requested by Council and Parliament in the 2003 EDCTP Decision, following the publication of this progress report the Commission will begin a **five-year evaluation of the Programme**. The results obtained will be taken into account when considering a decision on renewing the EDCTP Programme for the period 2010-2015.