

European Economic and Social Committee

INT/158

**Research programme/HIV-
AIDS – malaria – tuberculosis**

Brussels, 26 March 2003

OPINION

of the European Economic and Social Committee
on the

Decision 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 the developing countries, undertaken by a number of Member States and Norway

COM(2002) 474 final – 2002/0211 (COD)

On 19 September 2002 the Council decided to consult the European Economic and Social Committee, under Article 172(2) of the Treaty establishing the European Community, on the

Proposal for a Decision 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 the developing countries, undertaken by a number of Member States and Norway

COM(2002) 474 final – 2002/0211 (COD).

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 5 March 2003. The rapporteur was **Mr Bedossa**.

At its 398th plenary session (meeting of 26 March), the Economic and Social Committee unanimously adopted the following opinion:

1. Introduction

1. Speaking on the occasion of the launch of the European Community's sixth research and development framework programme (RDFP) for the four-year period starting on 1 January 2003, the primary purpose of which is to create a genuine European research area, **Commissioner Philippe Busquin** stated that the 21st century, even more than the one that had just ended, would be the century of knowledge. But Europe would only be able to respond to this challenge if it organised itself effectively.
2. He added that the programme was designed to establish a true internal market in knowledge in which researchers, knowledge and technologies circulated freely and a framework in which national and regional governments could coordinate their research policies and integrate their activities.
3. Overall, the draft decision presented by the Commission seems to be in line with this definition.

2. Background

1. **The major endemic diseases** (malaria and tuberculosis) and sexually transmitted diseases such as HIV/AIDS have increased considerably in poor countries, particularly in Africa.
2. Disease and poverty go hand in hand. Consequently, there is an urgent need on both public health and economic grounds to break this vicious circle.
3. The problem is global and at the centre of an international political debate; for several years now there have been repeated calls for action from all the international organisations.
4. The approach pursued within this broad policy framework is global, multi-sectoral and multi-factoral. For many years the poor countries have highlighted the excessively high price of key pharmaceuticals and the need for such countries to participate – at a level appropriate to them – in programmes of this kind through the development of effective and affordable medicinal products.
5. **The Member States and Associated States have jointly agreed** to develop clinical research activities targeting three diseases – HIV/AIDS, malaria and tuberculosis (TB) – since existing treatment protocols are cumbersome, too inflexible to respond to needs on the ground and still very expensive.

1. This situation is largely due to the following factors:

- the fragmentation of European clinical research;
- organisational and economic impediments to conducting clinical trials relevant to developing countries;
- the lack of the necessary skills and facilities in developing countries.

3. **The aim of the programme**

1. Fourteen EU Member States and Norway have agreed to launch a major new initiative, the European and Developing countries Clinical Trials Partnership (EDCTP), a partnership between Europe and the developing countries, particularly those in sub-Saharan Africa, which is designed to promote research and development activities aimed at combating HIV/AIDS, malaria and TB.
2. New vaccines, drugs and other products necessary for fighting these diseases are to be developed and, where possible, put on the market as quickly as possible.
3. This will be done by:
 - strengthening basic knowledge, the development of which is an absolute necessity;
 - networking and cooperation between the participating national programmes;
 - accelerating the development of new products, including the launch of clinical trials in the developing countries;
 - strengthening capacities for research into the treatment of these poverty-related diseases through cooperation between the EU and the developing countries.
4. The EDCTP programme will also promote public-private partnerships and the search for effective and affordable drugs and treatments, through support for clinical trials in the developing countries.
5. The participation of these countries is important for at least two reasons:
 - the aim must be to mobilise them as fully as possible because ultimately it is they who can make the choices that best reflect their needs;

- through representation in the EDCTP's executive structures, they can share in the running of the programme and ensure that its strategic priorities are implemented.

Two-thirds of the approved budget has been allocated for clinical trials. Another substantial part has been allocated for the implementation in Africa of structures supporting this research and necessary training of staff recruited in Africa.

4. **Community funding**

1. The development of new vaccines and drugs is very expensive. The European Union envisages a total investment of €200 million in the first five years of the programme. Although this is a large sum, it is necessary to demonstrate the strength of Europe's commitment to the programme.
2. The Community contribution of €200 million will have a leverage effect, enabling funding to be obtained from other sources, either the participating states themselves or private donors. As the Commission notes, the funding will act as a catalyst for initiating the first clinical trials, creating the necessary legal structure for the EDTCP and contributing significantly to capacity building in the developing countries.
3. Article 169 is used as the legal basis for implementing the programme as it allows:
 - the establishment of a common platform for the development of clinical research;
 - European research to contribute to the global fight against the three diseases in a coherent context with the organised participation of the developing countries;
 - the adoption of a time-scale that provides for the speedy setting up of the necessary machinery and the start of the first clinical trials by the end of 2003.

5. **General comments**

1. **The EESC endorses** the detailed description of the EDTCP programme and the targets set for it, namely:
 - networking and coordination of national programmes and activities conducted in the developing countries;

- accelerated development of new products to combat the three diseases;
 - visibility and sustainability of the EDTCP programme.
2. **The EESC notes** the general low level of activity which currently prevails in this field, which calls for a major new impetus to be given to research and development efforts. In fact:
 - there are very few links between existing national programmes;
 - the coherence and coordination of national research activities have not increased as expected, despite the decision of the Lisbon European Council in 2000;
 - giving research efforts a new impetus hinges on the joint execution of research programmes or parts of programmes and would not be feasible if it were necessary to wait for the setting-up of integrated projects or networks of excellence requiring a wide range of resources and the – sometimes difficult – coordination of efforts.
 3. **The EESC recognises** that the Community decision to intervene to combat the three diseases is necessary and urgent.
 4. Countries where the three diseases are rife are suffering severely at all levels, including the economy where poverty is becoming even more rampant.
 1. The clinical trials partnership between the EU and the developing countries will make it possible to combat poverty more effectively as the countries affected will be provided with sufficient resources to establish specific facilities and train the necessary personnel, for example by intensifying the transfer of knowledge that medical personnel responsible for conducting clinical research in Africa must acquire.
 2. The aim of this intervention is clear:
 - to try to bring an end to the fragmentation of European research;

- to contribute towards strengthening competitiveness in research and development on the global market;
- to implement European development and cooperation policies;
- to make national programmes more relevant by pooling them within the EDTCP.

5. **The EESC approves the way the programme's** funding is structured in line with its objectives:

- networking and coordination of European national programmes;
- support for the strengthening of capacities in the developing countries;
- measures to ensure the visibility and sustainability of the programme adopted.

6. **The EESC welcomes** the fact that the following are expressly provided for in the programme:

- follow-up arrangements; regular evaluation of the programme's progress;
- an annual report on the framework programme, presented to the European Parliament and the Council (Article 173);
- a range of anti-fraud measures to be carried out concurrently with the programme.

6. **Specific comments**

The EESC notes that:

1. The administrative procedures will be simplified, compared with the previous RDFP (Research and Development Framework Programme); the complexity and red tape were such that they acted as a disincentive to many research teams
2. The EDTCP seems to bring with it new and positive ideas: more autonomy and flexibility.
3. It will no longer be necessary, as was the case in the past, for each participant in a project to submit an analytical report on their activities. As regards its **coordinating role**, the programme will become the interface between the Commission and all the partners. It will be responsible for ensuring the scientific credibility of each project or network.

4. Evaluation procedures will be more flexible, owing to the Internet. Researchers must consider it an honour rather than a chore to evaluate an initiative like the EDTCP programme.
5. The programme is intended to be not only a bridge between researchers/developers and developing countries but also a tool in an ambitious and unifying initiative, guaranteeing, among other things, the transfer of technologies that can be used to develop solutions for the treatment and prevention of endemic diseases (malaria and tuberculosis) and sexually transmitted diseases in the countries concerned.
6. The programme will act as a catalyst for action and help to avoid fragmentation and duplication of human and financial resources in Member States' national programmes.
7. It would appear that, with this programme, the Commission has decided to put an end to the scattershot approach applied during the previous RDFP; instead there will be greater integration, more decisions on long-term cooperation and therefore fewer ad hoc alliances.
8. The EESC notes that the Commission has decided to select **only** three diseases: HIV/AIDS, malaria and TB. It is true that these are serious endemic diseases which are currently causing great devastation, especially HIV/AIDS.
9. However, the public health situation in the sub-Saharan regions of Africa is even more grave. The EESC would point out that there is a need for urgent action to combat other equally serious diseases such as childhood measles, cerebrospinal meningitis, trypanosomiasis, filariasis, kwashiorkor, pernicious anaemia, etc.
10. The EESC would stress that the most urgent aspect of the situation in Africa is the fact that it is economically impossible for these countries to obtain effective drugs and medicines that are already available.
11. Moreover, the EESC takes the view that, on the basis of these drugs, clinical research must also aim to develop **new treatment protocols** that are adapted to social and economic conditions in sub-Saharan Africa.
12. The EESC believes that **policies** for the prevention of these three diseases are an integral part of clinical research in the developing countries. These policies, which require substantial resources and skilled personnel, entail radical measures over a very long time scale in countries where the movement of persons is difficult for numerous reasons.

Brussels, 26 March 2003.

The President

The Secretary-General

of the
European Economic and Social Committee

of the
European Economic and Social Committee

Roger Briesch

Patrick Venturini

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