



COMMISSION OF THE EUROPEAN COMMUNITIES

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Modified 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

(presented by the Commission)

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1. SUBJECT OF THE PROPOSAL

In 2001, 14 Member States and Norway took the initiative of combining their research and clinical intervention work to combat AIDS, malaria and tuberculosis in the developing countries. This was the EDCTP research programme, intended to accelerate the development and evaluation of new vaccines and medicines in a partnership between Europe and several developing countries, particularly in Sub-Saharan Africa.

The Commission believed it would be in the Community's interest to be associated with this initiative, particularly in the context of creating the European Research Area. For this it proposed to use Article 169 of the Treaty, which provides that, in implementing the framework programme, and in agreement with the Member States concerned, the Community may make provision for participation in research programmes undertaken by several Member States.

The Commission's proposal is designed to enable such Community participation, for which a financial contribution of €200 million is provided for within the 6th framework programme of RTD (specific programme "Integrating and strengthening the European Research Area"). It is worth noting that this proposal represents the first concrete use of Article 169 of the Treaty.

2. BACKGROUND

- On 28 August 2002, the Commission adopted its proposal [COM(2002) 474 final].
- On 27 March 2003, Parliament adopted 35 amendments at first reading, reflecting the compromise text approved following various tripartite interinstitutional contacts.

3. THE COMMISSION'S OPINION ON PARLIAMENT'S AMENDMENTS

3.1 General assessment

Parliament's changes are in line with the approach proposed by the Commission, and provide useful clarifications for implementing the programme. The Commission can therefore accept all of them.

3.2 Examination of the amendments

Programme consistency and real partnership with the developing countries

Parliament wants to emphasise that the EDCTP programme is consistent with the various Community activities and the Union's overall policy in this area, and to underline the wish for a stronger partnership with and the genuine involvement of the developing countries in this initiative (*recitals 8, 10, 15a, 16 and 19a*). The Commission fully subscribes to this.

Taking account of co-existing infections and reference to the other "neglected" diseases

Parliament wants co-existing infections to be taken into account in the design of clinical trials (*recital 6 and Annex I*), and the other "neglected" diseases linked to poverty to be taken into account in the future initiatives to be launched (*recital 14*). The wording of these amendments avoids any risk of widening the scope of the EDCTP programme, which needs to be confined to the three main communicable diseases originally targeted. The Commission therefore accepts this wording, which clarifies the text of its original proposal.

Integration of other countries into the EDCTP programme

Parliament has inserted *recital 11a* (new) and *Article 5b* (new) in order to send a political signal to the associated countries and to third countries regarding their participation in the EDCTP programme. Similarly, *Article 5a* (new) will enable the future Member States to join the common structure after its creation with no procedural delay. The Commission cannot but subscribe to these amendments.

Consolidating, reinforcing and guaranteeing the impact and success of the programme

Parliament wants more explicit incorporation of the concepts of "promotion of technology transfer" to the developing countries and encouragement of the "participation of the private sector", especially industry, as well as the concepts of "ethical principles", "best clinical practices" and "principles of gender" (*recitals 12 and 19 and Article 2*). It also specifies that a significant part of the EDCTP budget is to be spent in the developing countries (*recital 12*). The Commission considers these amendments to be relevant and acceptable.

Common structure and governance model / Intellectual property rights

The amendment relating to *Article 2* further clarifies the common structure, the EDCTP governance model and the real and effective involvement of the developing countries. In addition, the reference to intellectual property rights should ensure the financial involvement of industry on favourable terms while providing the guarantees necessary for easy and affordable access to the results of the research activities and to the products emerging directly from them, to the benefit of the local populations. The Commission approves of these clarifications. The same applies to the wording on intellectual property rights, which is well balanced.

Description of the governance model

Parliament wishes to insert a new annex (*Annex Ia*) containing a concise description of the model of governance of the EDCTP programme and its components. While the Commission must point out that the creation of the common structure, and in particular that of the European economic interest grouping (EEIG), is a matter solely for the Member States and does not therefore constitute a precedent, it has no objection to raise regarding the substance of the amendment, and can accept it.

Obligations to inform Parliament

With the changes to *Article 5* and the insertion of *Article 5c* (new), Parliament wishes to draw attention, respectively, to the additional information it could require from the common structure (*Article 5*) and to the reference to the need for a summary of EDCTP activities in the annual report the Commission has to present pursuant to Article 173 of the Treaty (*new Article 5c*). The Commission considers that these additions and changes reflect Parliament's wish to be fully informed of the progress and evaluation of EDCTP programme activities, and it accepts them.

4. CONCLUSION

By virtue of Article 250(2) of the EC Treaty, the Commission hereby amends its proposal as specified above.