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

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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.