



**COUNCIL OF
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NOTE

From: The Presidency
To: Delegations
Subject: European & Developing Countries Clinical Trials Partnership

Delegations will find, in annex, a note from the Presidency on the above-mentioned topic.

**Information on a proposed second phase of EDCTP
(European & Developing Countries Clinical Trials Partnership)**

On 27-28 September 2010, the Belgian EU Council Presidency organised a member state meeting that aimed at reaching a consensus on a second phase (2011-2020) of the European and Developing Countries Clinical Trials Partnership (EDCTP). The EDCTP was the first European project under Article 169 (currently Article 185), which enables the EU to co-fund research programmes undertaken jointly by several Member States. This flagship programme was established in 2003 in response to the global health crisis caused by HIV/AIDS, tuberculosis and malaria, and implemented under the form of a European Economic Interest Group (EEIG) with headquarters in The Hague, The Netherlands and Cape Town, South Africa. The EDCTP brings together national research programmes on clinical trials of new and improved products against these diseases, of 14 member states and 2 associated countries in collaboration with African counterparts and like-minded organisations. The current programme (EDCTP-I) ended on 14 September 2010, and was granted a no-cost extension for initiated trials until May 2015. The EU has committed € 200 million in cash to EDCTP-I, to be matched by the member states for an equal amount, in cash or in kind.

The meeting was guided by a draft proposal, authored by a number of the current members of EDCTP, which outlined the achievements and experiences of EDCTP-I as well as the framework and ambitions of EDCTP-II. Internal and external experts and impact assessments acknowledge that the EDCTP resulted in the creation of a strong and innovative partnership with Africa as well as among EU member states. By March 2010, EDCTP had funded 142 projects, which involve 136 institutions from 29 sub-Saharan countries and 42 institutions from 14 European countries, and of which 68% are led by African project coordinators. Remaining challenges are the strengthening of joint programming between national programmes, the structuring of the African ownership, the establishment of more transparent co-funding procedures and the reinforcement of collaboration with industry and public-private partnerships. Moreover, since the initiation of EDCTP, the global health landscape has been enriched by many other initiatives and partnerships, interventions by emerging economies, and a growing commitment to country ownership and donor harmonisation as enshrined in the Declaration of Paris. The EU remains one of the largest donors in international health assistance and research, but fragmentation compromises its impact and visibility. Recent declarations emphasise more than ever the vital role of Africa in European policies; EDCTP is seen as a catalyst model for international collaborative programmes in the framework of the EU2020.

The participants, including EDCTP members, potential new members and representatives of the European Commission agreed on the following principles:

1. EDCTP-II should continue and expand its activities for at least another ten years, and build on the experience and achievements of EDCTP-I in terms of research and partnership.
2. EDCTP-II should maintain a focus on clinical trials against AIDS, malaria, tuberculosis in Sub-Saharan Africa, but have the flexibility to expand its scope gradually to tropical diseases, diagnostic tools and other phases of clinical and intervention research, and to link up with relevant activities in other regions.
3. EDCTP-II should be continued under Article 185, with emphasis on coordination and conduct of joint calls. It should take into account experiences gained under EDCTP-I and from other Article 185-programmes in order to streamline its governance structures and to simplify its co-funding mechanisms.
4. EDCTP-II should confidently establish its position in the global health landscape and reinforce synergies with European and national development agencies, African ministries of health and research, international and non-governmental organisations, donors and industry.
5. EDCTP-II should be based on unambiguous up-front commitments of member states to common objectives, to a truly joint work programme and to substantial financial contributions. These may consist of in-kind resources, nationally funded activities and cash contributions to a common pot. Full membership may initially be started by a core group of 7-10 countries that can ensure substantial upfront commitment at programme level, with associate members participating at project level.

6. EDCTP-II should actively seek expansion of the European partnership to new member states, and explore ways to allow full participation of African stakeholders in its governance structures.

 7. EDCTP-II should be governed by a long-term, transparent and flexible contract with the Commission, and foresee EU and member state contributions that take into account the increased intensity, the longer duration and the broader scope of EDCTP-II as compared to EDCTP-I. A detailed business plan, to be finalised by April 2011, should clearly identify member state commitments, budgets, timelines and deliverables that would condition the European Union contribution.
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