

Second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2): participation of the Union

2013/0243(COD) - 29/01/2014 - Committee report tabled for plenary, 1st reading/single reading

The Committee on Industry, Research and Energy adopted the report by Vicky FORD (ECR, UK) on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States.

The parliamentary committee recommended that the position adopted by the European Parliament at first reading under the ordinary legislative procedure should amend the Commission's proposal as follows:

Union's financial contribution: this shall be **EUR 648.85 million** (as opposed to EUR 683 million in the Commission proposal) matching the contributions of the participating states. This contribution shall be paid from the appropriations in the general budget of the Union allocated to the relevant parts of the Specific Programme implementing [Horizon 2020](#) Framework Programme and, in particular, from the appropriations under the specific objective "Health, demographic change and wellbeing".

Scope: Members suggested changing and extending the current scope of EDCTP1:

- further strengthening the capabilities in **developing countries** for sound conduct and management of clinical trials, in particular, the role and development of ethical review committees and the corresponding regulatory environment, the coordination, collaboration and, where appropriate;
- extending **public-private partnerships** (P2Ps) such as the Product Development Partnerships (PDPs), civil society, non-governmental organisations and foundations;
- making the **rules of governance** more clear and transparent.

Activities of the programme EDCTP2: the activities may include **activities undertaken by public or private not-for-profit research organisations** included in the national programme activities of participating states.

These activities must also contribute to:

- supporting clinical trial research and related activities on poverty-related diseases, in particular, HIV /AIDS, malaria, tuberculosis and **other poverty related and neglected diseases**, devoting special attention to neglected diseases that are already affecting Sub-Saharan Africa and Europe;
- launching joint actions with **industry and product development partnerships**, aiming at reinforcing national health systems and facilitating transfers of results to the population concerned;
- assuring **awareness, endorsement and acknowledgment** of the EDCTP2 Programme and its activities through advocacy and communication, not only at European Union level and in developing countries, but also at global level.

Conditions applicable to the Union's financial contribution: Members stressed the need to ensure that there be a strong coherence between the activities of the P2Ps and the research priorities defined in the Horizon 2020 Framework Programme, such as open access, equality between men and women and non-discrimination.

Rules for the participation and dissemination of results: an amendment sought to clearly establish that the Rules of Procedure apply and that projects are integrated and selected **via competitive calls**.

Members requested that all calls and opportunities to participate be widely advertised, including on the Commission's Horizon 2020 website which shall **include a chapter dedicated to EDCTP2**.

Audits: without prejudice to the independence or the role of the Court of Auditors of the European Union, the Commission may, in duly reasoned cases and in consultation with the participating states, decide to carry out *ex post* audits of indirect activities itself.

Evaluation: the Commission shall organise an **independent** interim evaluation of the EDCTP2 Programme by 30 June 2017 and send that report to the European Parliament and to the Council by 31 December 2017. The result of the independent interim evaluation of EDCTP2 shall be taken into account in the interim evaluation of Horizon 2020.

In order to respond to unforeseen situations or to new developments and needs the Commission may, following the interim evaluation of Horizon 2020, review, within the annual budgetary procedure, the budget of EDCTP2.