

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

2013/0243(COD) - 15/04/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 646 votes to 13, with 12 abstentions, a legislative resolution 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.

Parliament adopted its position at first reading under the ordinary legislative procedure. The amendments adopted in plenary were the result of a compromise between Parliament and Council. They amend the Commission's proposal as follows:

Union financial contribution: as stated in the Commission proposal, this would be **EUR 683 million**, to equal the contributions of Participating States.

It will be paid from the appropriations in the general budget of the Union allocated to the relevant parts of the Specific Programme implementing [Horizon 2020](#), and in particular from the appropriations under the specific objective "**Health, demographic change and wellbeing**".

To take account of the duration of the [Horizon 2020](#) Programme, all calls for proposals **should be launched by 31 December 2020**.

Scope: in [the Communication](#) of 27 February 2013 entitled "A decent life for all: ending poverty and giving the world a sustainable future", the Commission reaffirmed its commitment to doing its utmost to help achieve the MDG by 2015, and pointed out that EU-funded research under EDCTP1 had contributed to achieving the MDG.

Parliament and Council agreed to **amend and extend the current scope of EDCTP1 by :**

- **strengthening the capabilities** in developing countries for the 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, improving integration of European national programmes ;
- **extending collaboration** with other major public and private partners, including the pharmaceutical industry, and public-private partnerships such as the Product Development Partnerships ("PDPs"), civil society, non-governmental organisations and foundations;
- ensuring clear and transparent **rules of governance**.

EDCTP2 activities: activities may include activities undertaken by **public or private not-for-profit research organisations**, and new activities, including calls for proposals managed by the EDCTP2-IS.

The programme should contribute to the **reduction of the social and economic burden of poverty-related diseases** in developing countries, and in particular in sub-Saharan Africa, by accelerating the

clinical development of **effective, safe, accessible, suitable and affordable medical interventions** for such diseases, (such as drugs, microbicides or vaccines, including their delivery modality, follow up of treatment and prevention in the affected population as well as medical diagnostics to detect and monitor disease/health evolution.)

The **specific objectives** will be, inter alia :

- an increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, **including neglected ones**, and by the end of the programme to have delivered at least one new medical intervention, issued approximately 30 guidelines, and have progressed the clinical development of approximately 20 candidate medical interventions;
- establish the **research priorities** in an objective-orientated manner in order to accelerate results and contribute to the control and eradication of poverty-related diseases, including neglected ones;
- extend **international cooperation with other public and private partners** to ensure that the impact of all research is maximised and that synergies can be taken into consideration and achieve leveraging of resources and investments.

In order to reach the specific objectives, operational indicators and objectives would be monitored during the course of the EDCTP2 programme.

Agreements between the Union and the EDCTP2-IS : these must set out provisions for the publication of calls for proposals by EDCTP2, in particular on **the single portal for participants** as well as through other Horizon 2020 electronic means of dissemination managed by the Commission.

Audits: administrative burdens should be reduced for all parties. Double audits and disproportionate documentation and reporting should be avoided.

Evaluation: the Commission must carry out, with the assistance of independent experts, an interim evaluation of the EDCTP2 Programme by 30 June 2017 and report to Parliament and Council by 31 December 2017. The results of the independent interim evaluation should be taken into account in the interim evaluation of Horizon 2020.