

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

2013/0243(COD) - 15/05/2014 - Final act

PURPOSE: to contribute to the reduction of the social and economic burden of poverty-related diseases in developing countries, and in particular in sub-Saharan Africa.

LEGISLATIVE ACT: Decision No 556/2014/EU 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

CONTENT: this Decision is **part of a package of four legal acts for a new generation of public - private partnerships** that will allow large-scale, long-term innovation projects to be carried out under the umbrella of [Horizon 2020](#), the EU's research and innovation framework programme.

Three other public-public partnerships will be further developed on research programmes jointly undertaken by Member States with the participation of the Union in the areas of:

- a second research and development programme aimed at supporting research and development performing small and medium-sized enterprises ([‘Eurostars-2’](#));
- a programme on research and development on active and assisted living ([AAL programme](#));
- a European research and innovation programme on metrology ([EMPIR](#)) ;

Objective: the Decision establishes the rules and conditions for Union participation in the second European and Developing Countries Clinical Trials Partnership Programme (the ‘EDCTP2 Programme’), jointly undertaken by Austria, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Any Member State and any other country associated to Horizon 2020 may apply to join the programme, provided it fulfils the conditions regarding financial contribution.

Programme objectives: EDCTP1 (2003-2012) produced major achievements, and developed eight improved medical treatments, in particular for newborns, children and pregnant or breastfeeding women suffering from HIV/AIDS or malaria.

In extending the first programme, EDCTP-II will 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 poverty-related diseases in partnership with sub-Saharan countries.

The specific objectives are, 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; to have issued approximately 30 guidelines and approximately 20 candidate medical interventions;

- **strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials** in compliance with fundamental ethical principles and relevant national, Union and international legislation;
- **better coordination, alignment and, where appropriate, integration of relevant national programmes** to increase the cost-effectiveness of European public investments;
- **extended 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.

Union financial contribution: the Union's financial contribution, including EFTA appropriations, to the EDCTP2 Programme shall be up to **EUR 683 000 000** to equal the contributions of Participating States.

This contribution shall be paid from the appropriations 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'.

Implementation: the Participating States have agreed on the implementation structure for EDCTP2 Programme and have set up the EDCTP2-Implementation Structure (**'EDCTP2-IS'**). The EDCTP2-IS should be the recipient of the Union's financial contribution and should ensure the efficient implementation of the EDCTP2 Programme.

Calls for proposals should be launched at the latest by 31 December 2020. In duly justified cases they may be launched by 31 December 2021. Calls for proposals should also be published on the **single portal for participants** as well as through other Horizon 2020 electronic means of dissemination managed by the Commission.

In order to **protect the Union's financial interests**, the Commission should have the right to reduce, suspend or terminate the Union's financial contribution if the programme is implemented inadequately.

Evaluation: by 30 June 2017, the Commission shall carry out an interim evaluation of EDCTP-II with the help of independent experts. It shall send that report to the European Parliament and to the Council by 31 December 2017. The result of the interim evaluation of the programme shall be taken into account in the interim evaluation of Horizon 2020.

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