

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

2013/0243(COD) - 10/07/2013 - Legislative proposal

PURPOSE: to enable the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme jointly undertaken by several Member States.

PROPOSED ACT: Decision of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the European and Developing Countries Clinical Trials Partnership (EDCTP) was established in 2003 in response to the global health crisis caused by the three main poverty-related diseases - HIV/AIDS, malaria and tuberculosis - and to the EU's commitment to achieving the United Nation's Millennium Development Goals by 2015. The first EDCTP programme (EDCTP-I 2003-2012) is now beyond its active funding period.

EDCTP-I had major achievements and has so far developed eight improved medical treatments, in particular for new-borns, children or pregnant/lactating women suffering from HIV/AIDS or malaria. It has resulted in the launch of the first four African Regional Networks of Excellence promoting South-South cooperation on clinical research and more than 400 African researchers have been trained. It has also contributed to establishing the Pan-African Clinical Trials Registry and the African Vaccine Regulators Forum.

Despite the results and impact of EDCTP so far, the **health and socio-economic burden of poverty-related diseases persists and hinders the sustainable development of developing countries, in particular in sub-Saharan Africa**. More than one billion people, including 400 million children, are suffering from one or more poverty-related diseases, including neglected infectious diseases such as sleeping sickness and worm infections. HIV/AIDS alone kills an estimated 2 million people, while malaria and tuberculosis together kill an estimated 2.2 million people annually.

Following the recommendations from the independent interim evaluation of EDCTP-I, the Belgian EU Council Presidency proposed, in November 2010, **the launch of a second EDCTP joint programme (EDCTP-2) with at least ten years duration (2014-2024)**. On 15 June 2010, the European Parliament adopted a [resolution on progress towards achieving the Millennium Development Goals](#) (MDG) in which it 'asks the Commission, the Member States and developing countries to address MDG 5 (on improving maternal health), MDG 4 (on child mortality) and MDG 6 (on HIV/AIDS, malaria and tuberculosis) in a coherent and holistic way'.

IMPACT ASSESSMENT: the external interim evaluations of the EDCTP-I and the impact assessment of the future EDCTP-2 programme call for the programme to be continued but with the next programme lasting 10 years and covering a scope that extends to other poverty-related diseases (beyond HIV/AIDS, tuberculosis and malaria) and to all phases of clinical development. The geographical focus should continue to be on sub-Saharan Africa.

LEGAL BASIS: Articles 185 and Article 188(2) of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: the proposal for a decision concerns the participation of the Union in a **second European and Developing Countries Clinical Trials Partnership Programme (EDCTP-2)** jointly undertaken by Belgium, Denmark, Germany, Ireland, Greece, Spain, France, Italy, Luxembourg, the Netherlands, Austria, Portugal, Sweden and the United Kingdom, as well as Switzerland and Norway.

EDCTP2 shall contribute to the reduction of the social and economic burden of poverty-related diseases in developing countries, in particular in sub-Saharan Africa, by accelerating the clinical development of effective, safe and affordable medical interventions for poverty-related diseases, in partnership with sub-Saharan Africa.

EDCTP-2 seeks to achieve the following specific objectives:

- an increased number of new or improved medical interventions for HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, and by the end of the programme to have delivered (i) at least one new medical intervention; (ii) to have issued at least 30 guidelines for improved or extended use of existing medical interventions; and (iii) to have progressed the clinical development of at least 20 candidate medical interventions;
- strengthened cooperation with sub-Saharan African countries, in particular on building their capacity for conducting clinical trials;
- better coordination, alignment and integration of relevant national programmes to increase the cost-effectiveness of European public investments;
- extended international cooperation with other public and private funders;
- an increased impact due to effective cooperation with relevant European Union initiatives, including its development assistance.

EDCTP-2 has been conceived to complement the actions implemented under the European Development Funds and the Development Cooperation Instruments, and to respond to the Union's commitment to the 2012 Rio+20 conference conclusions on developing and achieving internationally agreed Sustainable Development Goals.

BUDGETARY IMPLICATION: the Union contribution shall be up to **EUR 683 million** at current prices including EFTA contribution. The envelope is in current prices. The Union contribution shall be made from the 'Health, demographic change and wellbeing' challenge, DG Research & Innovation envelope, as part of the implementation of Horizon 2020 – The Framework Programme for Research and Innovation. The maximum amount of Union contribution for administrative costs is up to EUR 41 million.