Basic information

2013/0243(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Decision	Procedure completed
Second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2): participation of the Union See also 2011/0401(COD) **Subject** 3.50.01.05 Research specific areas 4.20.02.06 Clinical practice and experiments 6.30.02 Financial and technical cooperation and assistance	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ITRE Industry, Research and Energy	FORD Vicky (ECR)	14/10/2013
	Shadow rapporteur CARVALHO Maria da Graça (PPE) RIERA MADURELL Teresa (S&D) HALL Fiona (ALDE) RIVASI Michèle (Verts/ALE)	

Committee for opinion	Rapporteur for opinion	Appointed
DEVE Development	PONGA Maurice (PPE)	11/11/2013
BUDG Budgets	The committee decided not to give an opinion.	
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Economic and Financial Affairs ECOFIN	3310	2014-05-06
Competitiveness (Internal Market, Industry, Research and Space)	3276	2013-12-03
Competitiveness (Internal Market, Industry, Research and Space)	3258	2013-09-26

European Commission	

Commission DG	Commissioner
Research and Innovation	GEOGHEGAN-QUINN Máire

European Economic and Social Committee

Key events

Date	Event	Reference	Summary
10/07/2013	Legislative proposal published	COM(2013)0498	Summary
10/09/2013	Committee referral announced in Parliament, 1st reading		
26/09/2013	Debate in Council		
23/01/2014	Vote in committee, 1st reading		
29/01/2014	Committee report tabled for plenary, 1st reading	A7-0064/2014	Summary
15/04/2014	Decision by Parliament, 1st reading	T7-0366/2014	Summary
15/04/2014	Results of vote in Parliament		
06/05/2014	Act adopted by Council after Parliament's 1st reading		
15/05/2014	Final act signed		
15/05/2014	End of procedure in Parliament		
07/06/2014	Final act published in Official Journal		

Technical information

Procedure reference	2013/0243(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Decision
Amendments and repeals	See also 2011/0401(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 185 Treaty on the Functioning of the European Union TFEU 188-p2
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	ITRE/7/13414

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE522.973	12/11/2013	
Amendments tabled in committee		PE522.974	05/12/2013	
Committee opinion	DEVE	PE521.824	18/12/2013	
Committee report tabled for plenary, 1st reading/single reading		A7-0064/2014	29/01/2014	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0366/2014	15/04/2014	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	00054/2014/LEX	15/05/2014	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2013)0498	10/07/2013	Summary
Document attached to the procedure	SWD(2013)0253	10/07/2013	
Document attached to the procedure	SWD(2013)0254	10/07/2013	
Commission response to text adopted in plenary	SP(2014)471	09/07/2014	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	IT_SENATE	COM(2013)0498	10/10/2013	
Contribution	PT_PARLIAMENT	COM(2013)0498	17/10/2013	
Contribution	ES_PARLIAMENT	COM(2013)0498	25/10/2013	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Decision 2014/0556
OJ L 169 07.06.2014, p. 0038

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.

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 Programmeand, 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.

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.

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.

ENTRY INTO FORCE: 27.06.2014.