REPORT

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 jointly undertaken by several Member States (COM(2013)0498 – C7-0222/2013 – 2013/0243(COD))

Committee on Industry, Research and Energy

Rapporteur: Vicky Ford
Symbols for procedures

* Consultation procedure
*** Consent procedure
***I Ordinary legislative procedure (first reading)
***II Ordinary legislative procedure (second reading)
***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in bold italics in the left-hand column. Replacements are indicated in bold italics in both columns. New text is indicated in bold italics in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in bold italics. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in bold italics and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.
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DRAFT EUROPEAN PARLIAMENT 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 jointly undertaken by several Member States (COM(2013)0498 – C7-0222/2013 – 2013/0243(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2013)0498),

– having regard to Article 294(2) and Article 185 and the second paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0222/2013),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,– having regard to the opinion of the European Economic and Social Committee of 10 December 2013¹,

– having regard to Rules 55 of its Rules of Procedure,

– having regard to the report of the Committee on Industry, Research and Energy and the opinion of the Committee on Development (A7-0064/2014),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

Proposal for a decision
Recital 2

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¹ Not yet published in the Official Journal.

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Parliament and of the Council of ... 2013\(^4\) (hereinafter ‘Horizon 2020 Framework Programme’) aims at achieving a greater impact on research and innovation by contributing to the strengthening of public-public partnerships, including through Union participation in programmes undertaken by several Member States in accordance with Article 185 of the Treaty.

\(^4\) OJ... [Horizon 2020 Framework Programme].

Parliament and of the Council\(^4\) (hereinafter ‘Horizon 2020 Framework Programme’) aims at achieving a greater impact on research and innovation by developing closer synergies, increasing coordination and avoiding unnecessary duplication with international, national and regional research programmes. Public-public partnerships, including Union participation in programmes undertaken by several Member States in accordance with Article 185 of the Treaty, should achieve those aims, meet the conditions specified in that Regulation, in particular in Articles 26 and be in full compliance with the General Principles, in particular the conditions relating to the communication and dissemination of information and open access.


Justification

Additions in line with Horizon 2020 Framework programme, in particular Recital 39 and Article 26. It is also important to guarantee the open access principles established in article 18 (b) of Horizon 2020 and article 28 on the communication and dissemination of information.

Amendment 2

Proposal for a decision

Recital 4

**Text proposed by the Commission**

(4) In 2009, independent experts adopted the report of the interim evaluation of

**Amendment**

(4) In 2009, independent experts adopted the report of the interim evaluation of
EDCTP1. The opinion of the expert panel was that EDCTP1 provided a unique platform for a genuine dialogue with African scientists and it has started to bridge the gap between North and South in building research capacities and in providing learning and working opportunities for young African researchers. Following this report, there are fundamental issues to be taken into consideration for a second European and Developing Countries Clinical Trials Partnership Programme (hereinafter "EDCTP2 Programme"): the current scope of EDCTP1 needs to be changed and extended; the integration of European national programmes should be further improved; collaboration with other major public and private funders, including the pharmaceutical industry, needs to be strengthened and extended; synergies with European external policy actions should be developed, in particular with EU development assistance; co-funding rules should be clarified and simplified; monitoring tools need to be strengthened.

- the current scope of EDCTP1 needs to be changed and extended;

- the capabilities in developing countries for sound conduct and management of clinical trials should, where necessary, be further developed and strengthened, in particular the role and development of ethical review committees and the corresponding regulatory environment, the coordination, collaboration and where appropriate integration of European national programmes should be further improved;

- collaboration with public and private partners, including the pharmaceutical industry, and public-private partnerships such as the PDPs (Product Development Partnerships), civil society, non-governmental organisations and foundations, needs to be strengthened and
extended;
- *there should be clear and transparent rules of governance;*
- synergies with European external policy actions should be developed, *specifically* with EU development assistance;
- co-funding rules should be clarified and simplified;
- monitoring tools need to be strengthened.

**Amendment 3**

**Proposal for a decision**

**Recital 5**

*Text proposed by the Commission*

(5) According to *Council Decision … /2013/EU of … 2013 establishing the Specific Programme implementing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)* further support may be provided to the EDCTP2 Programme.

*Amendment*

(5) According to *Regulation (EU) No 1291/2013 and Council Decision 2013/743/EU* further support may be provided to the EDCTP2 Programme.

*A reference not only to the Specific Programme but also to the Framework Programme should be included, which is important to evidence the compliance with Article 20 of the*
Framework Programme and the principles stated there.

Amendment 4
Proposal for a decision
Recital 5 a (new)

Text proposed by the Commission

(5a) The Union is a major funder of research into poverty-related diseases and neglected infectious diseases. The Commission and Member States contribute nearly one quarter (22%) of relevant global investment by governments. The Union is also a major player in global health. For example, the Commission and Member States provide about half the financing for the Global Fund To Fight AIDS, Tuberculosis and Malaria.

Amendment 5
Proposal for a decision
Recital 7

Text proposed by the Commission

(7) Despite the considerable results and achievements of EDCTP1, poverty-related diseases still represent a major obstacle to the sustainable development of developing countries due to their social and economic burden, especially in sub-Saharan Africa. Effective, safe and affordable medical treatments still do not exist for most poverty-related diseases and investment in clinical research remains inadequate as conducting clinical trials is costly and the return on investment is limited due to market failure. Moreover, European research activities and programmes are still often fragmented and thus either subcritical

Amendment

(7) Despite the considerable results and achievements of EDCTP1, poverty-related diseases still represent a major obstacle to the sustainable development of developing countries due to their social and economic burden, especially in sub-Saharan Africa. Effective, safe, suitable, accessible and affordable medical treatments tailored to developing countries' specific circumstances still do not exist for most poverty-related diseases and investment in clinical research remains inadequate as conducting clinical trials is costly and the return on investment is limited due to market failure. It should be pointed out
in scale or overlapping, whereas research
capacity and investment in developing
countries are inadequate.

that only 10% of global research funding
is allocated for the diseases which
account for 90% of the world’s
pathologies. Moreover, European research
activities and programmes are still often
fragmented and thus either subcritical in
scale or overlapping, whereas research
capacity and investment in developing
countries are inadequate.

Amendment 6
Proposal for a decision
Recital 7 a (new)

Text proposed by the Commission

(7a) Supporting the fight against poverty-
related diseases would also help to
safeguard the Union’s citizens from these
diseases as increasing global mobility
(including tourism), migratory movements
and shifts in geographic distribution of
these diseases mean that Europe may be
facing new or returning challenges from
these diseases.

Amendment 7
Proposal for a decision
Recital 11

Text proposed by the Commission

(11) The Commission presented a
communication on 31 March 2010\(^{10}\) on the
Union’s role in global health which calls
for a more coordinated approach among
Member States and across relevant policies
to identify and jointly address shared
global priorities for health research.

Amendment

(11) The Commission presented a
communication on 31 March 2010\(^{10}\) on the
Union’s role in global health which calls
for a more coordinated approach among
Member States and across relevant policies
to identify and jointly address shared
global priorities for health research. In that
communication, the Commission also
restates the need to promote equitable and
universal coverage of quality health
services plus effective and fair financing of research that benefits the health of all people.

Amendment 8
Proposal for a decision
Recital 11 a (new)

Text proposed by the Commission

(11a) In 2010, in its "Council Conclusions on the EU's role in global health", the Council called on the EU to promote effective and fair financing of research that benefits the health of all and ensures that innovations and interventions lead to affordable and accessible solutions. In particular, models that dissociate costs of R&D and the prices of medicines should be explored, including the opportunities for technology transfer to developing countries.

Amendment 9
Proposal for a decision
Recital 12 a (new)

Text proposed by the Commission

(12a) In its communication of 27 February 2013 entitled 'A decent life for all: ending poverty and giving the world a sustainable future'\(^{1a}\), 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 achievement of the MDG.
(13) In line with the objectives of Horizon 2020 Framework Programme, any Member State and any country associated to the Horizon 2020 Framework Programme should be entitled to participate in the EDCTP2 Programme. It must be ensured that projects receiving money from the Horizon 2020 Framework Programme are not in breach of international human rights law.

(13a) With a view to the overall aim of Horizon 2020 of achieving greater simplification and harmonisation of the European research and innovation funding landscape, public/public partnerships should establish simple governance models and avoid different sets of rules from Horizon 2020.
(13b) Barriers preventing the participation of newcomers to the programme should be identified and addressed. In this context the participation of SMEs, universities and research centres should be promoted.

Amendment 13
Proposal for a decision
Recital 14

Text proposed by the Commission

(14) The participating states intend to contribute to the implementation of EDCTP2 Programme during the period covered by the EDCTP2 Programme (2014 – 2024).

Amendment

(14) The participating states intend to contribute to the implementation of EDCTP2 Programme during the period covered by the EDCTP2 Programme (2014 – 2024). In order to take into account the duration of the Horizon 2020 Framework Programme for Research and Innovation, calls for proposals that require an EU contribution under this Programme should be launched by 31 December 2020.

Amendment 14
Proposal for a decision
Recital 15

Text proposed by the Commission

(15) A ceiling should be established for the Union's participation in EDCTP2 for the duration of Horizon 2020 Framework Programme. Within that ceiling, the Union contribution should be equal to the initial contributions committed by the participating states andArticle 1 of this Decision in order to achieve a high leverage effect and ensure a stronger integration of those states'

Amendment

(15) A ceiling should be established for the Union's participation in EDCTP2 for the duration of Horizon 2020 Framework Programme. Within that ceiling, the Union contribution should be equal to the contributions of the states referred to in Article 1 of this Decision in order to achieve a high leverage effect and ensure a stronger integration of those states'
That ceiling should also provide for matching the contributions from any other Member State or country associated to Horizon 2020 Framework Programme joining the EDCTP2 Programme during the Horizon 2020 Framework Programme.

Justification

It is important to have flexibility in the way the EDCTP2 funds are spent.

Amendment 15

Proposal for a decision
Recital 16

Text proposed by the Commission

(16) The Union's financial contribution should be subject to formal commitments from the participating states to contribute to implement the EDCTP2 Programme and their fulfilment.

Amendment

(16) The Union's financial contribution should be subject to formal commitments from the participating states to contribute to implement the EDCTP2 Programme and their fulfilment. In particular, clinical trials should only receive a financial contribution from the Union where they are performed in accordance with the Helsinki declaration and where the same standards for data transparency apply as in Regulation (EU) N:o .../2014 [Regulation in document COD 2012/0192].

Amendment 16

Proposal for a decision
Recital 16 a (new)

Text proposed by the Commission

(16a) It is essential that informed consent for clinical trials conducted in developing countries is always obtained in a way that is truly informed and truly voluntary.
Justification

Guidelines for obtaining informed consent are often difficult to implement because of low literacy levels, socio-economic and cultural factors. The local ethics committees, whose role is critical in informed consent, are often weak, ill-equipped or non-existent in some countries. Many participants may have incomplete understanding of the various aspects of the clinical trials due to language barriers, the way information is disclosed or terms used for informed consent documents.

Amendment 17
Proposal for a decision
Recital 27 a (new)

Text proposed by the Commission

(27a) It is also important that the activities conducted under the EDCTP2 Programme should meet developing countries' needs and match the Union’s global health commitments and that those activities should be consistent with the Union's development policy actions, as provided for by Article 208 of the Treaty on the Functioning of the European Union.

Amendment 18
Proposal for a decision
Recital 28

Text proposed by the Commission

(28) Since the objectives of this Decision, namely 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 by accelerating the clinical development of effective, safe and affordable medical interventions for poverty-related diseases, cannot be sufficiently achieved by the Member States due to the lack of necessary

Amendment

(28) The objectives of this Decision, namely 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 by accelerating the clinical development of effective, safe, accessible, appropriate and affordable medical interventions for poverty-related and neglected diseases which are tailored to the specific needs
critical mass to be achieved, both in human and financial terms, and can therefore, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary for that purpose.

**Amendment 19**

**Proposal for a decision**

**Recital 28 a (new)**

*Text proposed by the Commission*

(28a) The participant guarantee fund set up under Regulation No 1906/2006/EC of the European Parliament and of the Council¹ and managed by the Commission has proved to be an important safeguard mechanism which mitigates the risks associated with the amounts due and not reimbursed by defaulting participants. However the new participant guarantee fund established under Regulation (EU) No 1290/2013 of the European Parliament and of the Council² may not be legally appropriate to EDCTP2, and the Commission should therefore come forward with proposals to ensure that the fund, or a similar fund, is available to cover all funding bodies related to EDCTP2.

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Amendment 20

Proposal for a decision
Recital 28 b (new)

Text proposed by the Commission

Amendment

(28b) The results of clinical trials and other research activities carried out under the EDCTP2 programme should be disseminated as soon as possible by appropriate means and in compliance with Regulation (EU) No 1290/2013, and in particular open access shall apply with regard to the dissemination through research publications.

Amendment 21

Proposal for a decision
Article 2

Text proposed by the Commission

Amendment

Article 2
Union's financial contribution
1. The maximum Union financial

1. The maximum Union financial
contribution, including EFTA appropriations, to the EDCTP2 Programme shall be EUR 683 million, as follows:

(a) EUR 594 million to equal the contributions of participating states listed in article 1.1;

(b) EUR 89 million to equal the contributions of any other Member State or any other country associated to Horizon 2020 Framework Programme participating in the EDCTP2 Programme in accordance with Article 1.2.

2. The 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, established by Decision …/2013/EU in accordance with Article 58(1)(c)(vi) and Articles 60 and 61 of Regulation (EU, Euratom) No 966/2012.

3. Up to 6% of the Union’s financial contribution may be used by the implementing structure of EDCTP2 (hereinafter "EDCTP2-IS") to cover its administrative costs.

Amendment 22
Proposal for a decision
Article 3 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(aa) the demonstration by the Participating States that EDCTP2 is set up in accordance with the objectives and research priorities of the health research challenge laid down in Regulation (EU) No 1291/2013 and Council Decision
Justification
This addition stresses that there should be a strong coherence between the activities of the P2Ps and the research priorities defined in the Horizon 2020 Framework Programme.

Amendment 23
Proposal for a decision
Article 3 – paragraph 1 – point a b (new)

Text proposed by the Commission

Amendment
(ab) the demonstration by the Participating States that EDCTP2 is set up in accordance with the general principles governing the Horizon 2020 Framework;

Justification
This addition stresses the important adherence of the P2Ps to the general principles applying to the Horizon 2020 framework such as open access, gender equality and non-discrimination that have been agreed upon during the Horizon 2020 negotiations.

Amendment 24
Proposal for a decision
Article 3 – paragraph 1 – point a c (new)

Text proposed by the Commission

Amendment
(ac) the demonstration by the Participating States that EDCTP2 is set up in accordance with the conditions laid down in Article 20 of Regulation (EU) No 1291/2013;

Justification
This addition stresses the important principles that have been agreed on during the Horizon 2020 negotiations regarding P2Ps and what they should deliver.
Amendment 25
Proposal for a decision
Article 3 – paragraph 1 – point e

Text proposed by the Commission
(e) the commitment by each participating state to contribute to the financing of the EDCTP2 Programme.

Amendment
(e) the commitment by each participating state to contribute in cash and in kind to the financing of the EDCTP2 Programme.

Justification
Seeks alignment with the H2020 Framework Programme Regulation

Amendment 26
Proposal for a decision
Article 4 – paragraph 1 – subparagraph 2

Text proposed by the Commission
Activities may include national programme activities of participating states and new activities, including calls for proposals managed by the EDCTP2-IS.

Amendment
Activities may include activities undertaken by public or private not-for-profit research organisations included in the national programme activities of participating states and new activities, including calls for proposals managed by the EDCTP2-IS.

Justification
At the request of Fondation Merieux.

Amendment 27
Proposal for a decision
Article 4 – paragraph 1 – subparagraph 3

Text proposed by the Commission
Activities shall be included in the work plan of the EDCTP2 Programme adopted annually by the EDCTP2-IS following the

Amendment
Activities shall be included in the work plan of the EDCTP2 Programme adopted annually by the EDCTP2-IS following the
positive outcome of their external evaluation by international peer review based on Article 14(1) of Regulation (EU) No … [Rules for the participation and dissemination in Horizon 2020], and with regard to their contribution to the objectives of the EDCTP2 Programme.

Amendment 28
Proposal for a decision
Article 5 – paragraph 1 – point b

Text proposed by the Commission
(b) in kind contributions consisting of the costs incurred by the participating states in implementing activities included in the work plan referred to in Article 4(1) or in relation to the administrative budget of the EDCTP2-IS.

Amendment
(b) in kind contributions consisting of the costs incurred by the participating states in implementing activities included upfront in the work plan referred to in Article 4(1) or in relation to the administrative budget of the EDCTP2-IS.

Amendment 29
Proposal for a decision
Article 6 – paragraph 1

Text proposed by the Commission
1. Regulation (EU) No … [Rules for the participation and dissemination in Horizon 2020] shall apply to indirect actions selected and funded by EDCTP-IS in accordance with the work plan referred to in Article 4(1) or following calls for proposals managed by EDCTP2-IS. In accordance with that Regulation, the EDCTP2-IS shall be considered a funding body and shall provide financial support to indirect actions in accordance with Annex II to this Decision.

Amendment
1. Regulation (EU) No 1290/2013 shall apply to indirect actions selected and funded by EDCTP-IS following calls for proposals managed by EDCTP2-IS. In accordance with that Regulation, the EDCTP2-IS shall be considered a funding body and shall provide financial support to indirect actions in accordance with Annex II to this Decision.
Justification

Seeks to avoid ambiguity that the RfP apply and that projects are integrated and selected via competitive calls

Amendment 30

Proposal for a decision
Article 6 – paragraph 4

Text proposed by the Commission

4. Where such an activity is included in the workplan, EDCTP2-IS may launch joint calls with third countries or their scientific and technological organisations and agencies, with international organisations or with other third parties, in particular non-governmental organisations, in accordance with the rules developed based on Article 11 of Regulation (EU) No … [Rules for the participation and dissemination in Horizon 2020].

Amendment

4. Where such an activity is included in the workplan, EDCTP2-IS may launch joint calls with third countries or their scientific and technological organisations and agencies, with international organisations or with other third parties, in particular non-governmental organisations and product development organisations, in accordance with the rules developed based on Article 11 of Regulation (EU) No 1290/2013.

Amendment 31

Proposal for a decision
Article 6 – paragraph 4 a (new)

Text proposed by the Commission

4a. The participant guarantee fund established under Regulation (EU) No 1290/2013 may not be legally appropriate to EDCTP2, and the Commission shall therefore come forward with proposals to ensure that the fund, or a similar fund, is available to cover all funding bodies related to EDCTP2.

Amendment

Amendment 32

Proposal for a decision
Article 6 – paragraph 4 b (new)
Text proposed by the Commission

(4b) In accordance with the principles of transparency and non-discrimination as laid out in Article 60(1) and 128(1) of Regulation (EU, Euratom) No 966/2012, calls for proposals organised by EDCTP2 shall be published on the web-based Horizon 2020 Participant Portal.

Justification

During the Horizon 2020 trilogue negotiations the institutions agreed to promote a greater coherence of all call possibilities financed under Horizon 2020. To this effect, the Commission promised to promote the publication of CfPs organised by PPPs and P2Ps on the Horizon 2020 Participant Portal. This amendment aims to turn a self-obligation into a legal requirement, guaranteeing simple and accessible information for applicants.

Amendment 33

Proposal for a decision
Article 9 – paragraph 2

Text proposed by the Commission

2. The Commission may decide to carry out the audits referred to in paragraph 1 itself.

Amendment

2. 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 the audits referred to in paragraph 1 itself.

Amendment 34

Proposal for a decision
Article 11 – paragraph 3 a (new)

Text proposed by the Commission

3a. All calls and opportunities to participate shall be widely advertised, including on the Commission’s Horizon 2020 website which shall include a chapter dedicated to EDCTP2.

Amendment

3a. All calls and opportunities to participate shall be widely advertised, including on the Commission's Horizon 2020 website which shall include a chapter dedicated to EDCTP2.
Justification

In order to increase participation generally and of new-comers in particular, the dissemination of information relating to calls and application procedures should be well-advertised, including through the Horizon2020 website.

Amendment 35

Proposal for a decision
Article 12 – paragraph 1

Text proposed by the Commission

1. By 31 December 2017 the Commission shall conduct an interim evaluation of the EDCTP2 Programme. The Commission shall prepare a report on that evaluation which includes conclusions of the evaluation and observations by the Commission. The Commission shall send that report to the European Parliament and to the Council by 30 June 2018.

Amendment

1. By 30 June 2017 the Commission shall organise an independent interim evaluation of the EDCTP2 Programme. The Commission shall prepare a report on that independent evaluation which includes conclusions of the evaluation and observations by the Commission. The Commission shall 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 as referred to in Article 32(3) of Regulation (EU) No 1291/2013 review, within the annual budgetary procedure, the budget of EDCTP2.

Amendment 36

Proposal for a decision
Annex I

Text proposed by the Commission

EDCTP2 shall contribute to the following

Amendment

EDCTP2 shall contribute to the following
objectives:

(1) General Objective
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.

(2) Specific Objectives
In order to contribute to the general objective, EDCTP2 shall achieve the following specific objectives:

(a) 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 at least one new medical intervention; to have issued at least 30 guidelines for improved or extended use of existing medical interventions; and to have progressed the clinical development of at least 20 candidate medical interventions;

(b) 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, including the Charter of Fundamental Rights of the European Union, the European Convention on Human Rights and its Supplementary Protocols, the World Medical Association’s Declaration of Helsinki of 2008 and the standards on good clinical practice adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);

(c) better coordination, alignment and
integration of relevant national programmes to increase the cost-effectiveness of European public investments; where appropriate, integration of relevant national programmes to increase the cost-effectiveness of European public investments. Moreover, the research priorities should be established in an objective-orientated manner in order to accelerate results and contribute to the control and eradication of poverty-related and neglected diseases.

(d) extended international cooperation with other public and private funders;

(d) 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;

(e) an increased impact due to effective cooperation with relevant European Union initiatives, including its development assistance.

(e) better coordination, alignment and, where appropriate, integration with relevant European Union initiatives, in particular its development assistance and other key initiatives to enhance research and development for poverty-related diseases, product development partnerships and other government-led programmes in order to better take advantage of synergies, create a more complete innovation chain from clinical trials to treatment delivery and increase the effectiveness of European public investments. In this context, synergies between EDCTP2 and the European Development Fund are essential.

(3) Operational Objectives

In order to reach the specific objectives set out in point 2, the following operational objectives, including indicative targets, shall be met by the end of the EDCTP2 programme in 2024:

(a) Support clinical trials on new or improved medical interventions for poverty-related diseases through partnerships between European and developing countries, in particular sub-

In order to reach the specific objectives set out in point 2, the following indicators shall be monitored during the course of the EDCTP2 programme.

(3) Operational Indicators and Objectives
Saharan Africa:

**Target**: increase the number of supported clinical trials to at least 150 compared to 88 under EDCTP1.

**Indicator**: increase the number of supported clinical trials, compared to 88 under EDCTP1, that lead to new products, processes, methodologies, diagnostics, treatments or preventions.

**Target**: sustain or increase the proportion of clinical trials funded by the EDCTP2-IS with African leadership to at least 50%.

**Indicator**: sustain or increase the proportion of clinical trials funded by the EDCTP2-IS with African leadership.

**Target**: Increase the number of peer-reviewed scientific articles published to at least 1000.

**(b) Support research capacity-building activities in sub-Saharan Africa enabling clinical trials to be conducted and helping to reduce the brain drain:**

**Target**: sustain or increase the number of sub-Saharan African countries supported by the EDCTP2 to at least 30.

**Indicator**: aim to sustain or increase the participation of sub-Saharan African countries in the EDCTP2.

**Target**: increase the number of fellowships to sub-Saharan African researchers and MSc/PhD students to at least 600 compared to 400 under EDCTP1, with at least 90% of them continuing their research career in sub-Saharan Africa for at least one year after their fellowship.

**Indicator**: increase the number of fellowships to sub-Saharan African researchers and MSc/PhD students from 400 under EDCTP1, strongly encouraging and supporting them to continue their research career in sub-Saharan Africa following their fellowship.

**(c) Develop a common research agenda, criteria for priority setting and common evaluation:**

**Target**: at least 50% of the public investment by participating European states are integrated, aligned or coordinated

**Indicator**: increase the number of capacity-building activities supported for conducting clinical trials in sub-Saharan Africa from 74 under EDCTP1.

**(c) Develop a research agenda for EDCTP2 based on common criteria for priority setting and common evaluation**
through the EDCTP2 Programme.

(d) Ensure efficiency of the implementation of the EDCTP2 Programme:

Target: administrative costs are below 5% of the EDCTP2-IS budget.

(e) Establish cooperation and launch joint actions with other public and private funders.

**Target:** increase the contributions received from developing countries to at least EUR 30 million compared to EUR 14 million under EDCTP1.

**Target:** obtain additional contributions, either public or private, of at least EUR 500 million compared to EUR 71 million under EDCTP1.

(f) Establish cooperation and launch joint actions with Union, national and international development assistance initiatives in order to ensure complementarity and increase the impact of the results of EDCTP2-funded activities.

**In particular and where appropriate, coordinate EDCTP2-funded activities with initiatives resulting from the WHO Consultative Expert Working Group (CEWG) process on financing and coordination of R&D.**

**Target:** obtain additional contributions, either public or private, of at least EUR 500 million compared to EUR 71 million under EDCTP1.

(fa) Raise the profile of actions carried out under the EDCTP2 Programme at European and global level, in particular in developing countries, by making use of political dialogue fora such as the ACP-EU Joint Parliamentary Assembly or EU-Africa Summits.

**Amendment 37**

**Proposal for a decision**

**Annex II**
Text proposed by the Commission

(1) Activities

The EDCTP2 Programme shall include the following activities:

(a) promoting networking, coordination, alignment, cooperation and integration of national research programmes and activities on poverty-related infectious diseases at scientific, management and financial level;

(b) supporting clinical trial research and related activities on poverty-related diseases, in particular HIV/AIDS, malaria, tuberculosis and neglected infectious diseases;

(c) fostering capacity development for clinical trials and related research in developing countries through grants for: career development of junior/senior fellows, promoting mobility, staff exchange grants, research training networks, strengthening ethics and regulatory bodies, mentoring and partnerships at individual or institutional level;

(d) establishing cooperation and launching joint actions with other public and private funders;

(e) assuring awareness, endorsement and acknowledgment of the EDCTP2 Programme and its activities through advocacy and communication.

(2) Programme definition and

Amendment

(1) Activities

The EDCTP2 Programme shall include the following activities:

(a) promoting networking, coordination, alignment, collaboration, cooperation and integration of national research programmes and activities on poverty-related and neglected diseases at scientific, management and financial level;

(b) supporting clinical trial research and related activities on poverty-related diseases, in particular, HIV/AIDS, malaria, tuberculosis and other poverty related and neglected diseases. Special attention should be devoted to neglected diseases that are already affecting Sub-Saharan Africa and Europe;

(c) fostering capacity development for clinical trials and related research in developing countries, in particular in Sub-Saharan Africa, through grants for: career development of junior/senior fellows, promoting mobility, staff exchange grants, research training networks, strengthening ethics and regulatory bodies, mentoring and partnerships at individual or institutional or regional level;

(d) establishing cooperation and launching joint actions with other public and private funders, including industry and product development partnerships, aiming at reinforcing national health systems and facilitating transfers of results to the population concerned;

(e) 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.
The EDCTP2 Programme shall be implemented by the EDCTP2-IS on the basis of an annual work plan and a multiannual strategic work plan prepared by the EDCTP2-IS and adopted by the General Assembly of the EDCTP2-IS following international peer-review and subject to the prior approval by the Commission.

The annual work plan shall identify topics and activities to be implemented, including calls for proposals to be launched by EDCTP-IS to select and fund indirect actions, as well as the budgets and EDCTP2 funding for those topics and activities.

The annual work plan shall differentiate between the activities funded or co-funded by the Union and those funded by participating states or other revenues.

The multiannual strategic work plan shall set a common strategic research agenda which shall be prepared and updated on an annual basis.

EDCTP2-IS shall monitor the implementation of the activities included in the work plan, including indirect actions selected through calls for proposals it manages. It shall allocate and manage funding to these in accordance with this Decision and the effective implementation of activities selected and identified in the previous work plans.

(3) Deliverables expected from the implementation of the EDCTP2
An annual report shall be provided by EDCTP2-IS, which shall give a detailed overview of the implementation of the EDCTP2 Programme. That overview shall provide information on each activity selected in accordance with the work plan, including indirect actions selected through calls for proposals managed by EDCTP-IS. Such information shall include a description of each activity, including indirect action, its budget, the value of the funding allocated to it if any, and its status.

With regards to calls managed by EDCTP-IS, the annual report shall moreover include information on the number of projects submitted and selected for funding, the detailed use of the Union financial contribution, the distribution of national and other contributions, the types of participants, country statistics, brokerage events and dissemination activities.

The annual report shall also include information on the progress towards achieving the EDCTP2 Programme objectives set out in Annex I.

In addition, the EDCTP2-IS shall provide any report and information foreseen by this Decision and the agreement concluded with the Union.

Amendment 38

Proposal for a decision

Annex III

Text proposed by the Commission

The organisational structure of the

Amendment

The organisational structure of the
EDCTP2 Programme shall comprise the following:

(1) The EDCTP2-IS shall be governed by a general assembly (hereinafter "GA"), in which all participating states are represented.

The GA’s principal responsibility shall be to ensure that all necessary activities are undertaken to achieve the objectives of the EDCTP2 Programme, and that its resources are properly and efficiently managed. It shall adopt the annual work plan.

The GA shall decide by consensus. Failing consensus, the GA shall take its decisions by a majority of at least 75% of the votes.

The Union, represented by the Commission, shall be invited to all GA meetings as an observer, and shall receive all necessary documents. It may take part in discussions.

(2) The GA shall appoint a management board that shall supervise the secretariat of the EDCTP2-IS (hereinafter "SEC") established by the GA as the executive body of the EDCTP2 Programme.

SEC shall have the following tasks:

(a) represent the EDCTP2-IS;
(b) provide support to the GA;

(c) implement the EDCTP2 Programme and manage those of its activities entrusted to EDCTP2-IS by the annual work plan

(d) monitor and report on the implementation of the EDCTP2 Programme;
(e) manage the financial contributions from the participating states, the Union and any third party, and report on their use to the GA and the Union;
(f) increase the visibility of the EDCTP2 Programme through advocacy and
communication;

(g) liaise with the Commission in accordance with the delegation agreement referred to in Article 7.

(3) A Scientific Advisory Committee (hereinafter ‘SAC’) shall advise the GA on the strategic priorities of the EDCTP2 Programme.

The SAC shall be appointed by the GA and consist of European and African independent experts competent in areas relevant to the EDCTP2 Programme.

The SAC shall have the following tasks:

(a) advise the GA on priorities and strategic needs regarding clinical trials in Africa

(b) review and advise the GA on the content, scope and dimension of the EDCTP2 draft annual work plan, including diseases covered and approaches to be adopted, from a scientific and technical standpoint

(c) review the scientific and technical aspects of the implementation of the EDCTP2 Programme and deliver an opinion on its annual report

In exercising its tasks, the SAC shall monitor and promote high standards of ethical conduct of clinical trials and engage with vaccine regulatory authorities.

The SAC may recommend to the GA the setting up of scientific subcommittees, task forces and working groups.

The GA shall establish the number of SAC members, their voting rights and the modalities of their appointment in

communication;

(f) liaise with the Commission in accordance with the delegation agreement referred to in Article 7.

(3) A Strategic Advisory Committee (hereinafter 'SAC') shall provide strategic and scientific advice to the GA, the Board and the SEC.

The SAC shall be appointed by the GA and consist of European and African independent experts competent in areas relevant to the EDCTP2 Programme. Its composition shall seek to achieve gender equality in accordance with Article 15 of the Regulation (EU) No 1291/2013.

The SAC shall have the following tasks:

(a) advise the GA on priorities and strategic needs regarding clinical trials in Africa

(b) advise the GA on the content, scope and dimension of the EDCTP2 draft annual work plan, including diseases covered and approaches to be adopted, from a scientific and technical standpoint

(c) review the scientific and technical aspects of the implementation of the EDCTP2 Programme and deliver an opinion on its annual report

(ca) advise, where appropriate, on target product profiles in order to guide investment decisions according to agreed priorities.

In exercising its tasks, the SAC shall monitor and promote high standards of ethical conduct of clinical trials and engage with vaccine regulatory authorities.

The SAC may recommend to the GA the setting up of scientific subcommittees, task forces and working groups.

The GA shall establish the number of SAC members, their voting rights and the modalities of their appointment in
accordance with Article 37 of Regulation (EU) No ... [Rules for the participation and dissemination in Horizon 2020]. The GA may set up specialised working groups under the SAC with additional independent experts for specific tasks.

accordance with Article 37 of Regulation (EU) No 1290/2013. The GA may set up specialised working groups under the SAC with additional independent experts for specific tasks.
EXPLANATORY STATEMENT

The rapporteur is supportive of the general objective of EDCTP2 to accelerate the clinical development of effective, safe and affordable medical interventions for poverty-related diseases. She recognises the necessity of working in partnership with developing countries such as sub-Saharan Africa to tackle the negative impacts of poverty-related diseases which affect 1 billion people and tragically cause such huge loss of life. She also recognises the impact that the spread of poverty-related diseases has on the wider world and Europe in particular where many of these illnesses have been eradicated.

The rapporteur believes that despite the relative successes of EDCTP1, given the humanitarian aspect of this important work getting value for money needs to be a top priority to make sure that the best possible outcomes are achieved. Coordinating closely with other organisations from public, private and voluntary sectors with similar objectives is also vital, not only to maximise the investments of Member States but also to minimise overlap and duplication. The rapporteur recognises that different participating countries will frequently have their own investment and research programmes and welcomes diversity as often this can bring great benefits. She recommends a flexible approach to co-funding which will allow countries to participate with in kind contributions.

There needs to be a clear audit trail for EU spending so EDCTP must be held accountable for the public money it spends. The Commission should have the right to carry out audits but this must not prejudice the independence or the role of the EU Court of Auditors.

Although the rapporteur is supportive of the General and Specific Objectives of the EDCTP programme she is concerned that certain targets proposed as "Operational Objectives" may give a false sense of achievement, might be open to manipulation and may not reflect actual success of the primary ambition to find vaccines, treatments and cures, and improved procedures or processes. For this reason the rapporteur suggests changing hard "targets" on the number of trials and number of countries involved to "indicators".

Increasing participation should be a priority and new-comers should be able to access information on funding opportunities easily. The rapporteur suggests that a way to achieve this would be to ensure that a separate and clearly signposted chapter on the Horizon 2020 website is reserved exclusively for the dissemination of information relating to applications for and information on EDCTP2 trials. Where possible, opportunities should be well advertised in advance. The rapporteur is also committed to ensuring that the open access principles established in Horizon 2020 relating to publications is applied to EDCTP2. The rapporteur welcomes suggestions on additional measures relating to transparency.

The rapporteur is not proposing any amendments to the list of diseases to be addressed, and recommends avoiding either a closed or a longer list. The researchers involved will not know at the outset what their conclusions will be. Therefore, maintaining flexibility will be important so that projects that show the most potential are supported and money is not spread out to projects merely because they appear on a list. She proposes deleting references which may limit the scope to only "infectious" diseases.
Finally, the rapporteur would welcome the thoughts of other parties on the proposed length of EDCTP2. She has not submitted any amendments at this stage. She understands that clinical trial projects of this nature may need a longer time to complete and that the three extension years post-2020 may be vital to a project's success. However, she believes that all funds should be committed by 2020 and the substantial majority spent by year end 2020.
18.12.2013

OPINION OF THE COMMITTEE ON DEVELOPMENT

for the Committee on Industry, Research and Energy

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 jointly undertaken by several Member States (COM(2013)0498 – C7-0222/2013 – 2013/0243(COD))

Rapporteur: Maurice Ponga

SHORT JUSTIFICATION

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 commitments in connection with the United Nations' Millennium Development Goals.

The EDCTP Programme, with EUR 200 million in cofunding from the Commission, has involved 14 EU Member States, Norway, Switzerland and 48 countries in sub-Saharan Africa.

Between 2003 and 2013, eight improved medical treatments have been developed, four African regional networks of excellence for clinical research have been launched, and more than 400 African researchers have been trained.

HIV/AIDS, malaria and tuberculosis alone still kill five million a year, however. Accordingly in July 2013, further to the Belgian Council Presidency's November 2010 proposal to extend the programme, the Commission submitted a proposal for an EDCTP2 Programme for a further 10-year period.

New ambitious objectives have been set for the EDCTP2 Programme:
- covering more diseases and increasing the number of medical interventions;
- stepping up cooperation with countries in sub-Saharan Africa;
- improving coordination of national programmes, bringing them more into line with each other and making them more integrated;
- extending international cooperation to other public and private funders;
- ensuring consistency with other EU policies.
The EU’s maximum financial contribution would be increased to EUR 683 million (under the Horizon 2020 programme) in addition to the contributions from participating states and public or private bodies.

Your rapporteur welcomes the fact that the programme is to be extended, the increased EU budget allocation for it and the expanded range of actions fundable under EDCTP2.

Your rapporteur is also pleased that there is a willingness to increase synergies between the EU’s various actions, in particular development policy actions. In that respect, however, the Commission proposal should be amended so as to restate the fact that consistency between EU policies and development goals is a core EU principle.

Lastly, your rapporteur is proposing to amend the Commission proposal to bring about greater clarity as to the EU’s financial contribution and the EDCTP2 Programme's objectives.

AMENDMENTS

The Committee on Development calls on the Committee on Industry, Research and Energy, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a decision
Recital 4

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
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<tr>
<td>(4) In 2009, independent experts adopted the report of the interim evaluation of EDCTP1(^8). The opinion of the expert panel was that EDCTP1 provided a unique platform for a genuine dialogue with African scientists and it has started to bridge the gap between North and South in building research capacities and in providing learning and working opportunities for young African researchers. Following this report, there are fundamental issues to be taken into</td>
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consideration for a second European and Developing Countries Clinical Trials Partnership Programme (hereinafter "EDCTP2 Programme"): the current scope of EDCTP1 needs to be changed and extended;

the integration of European national programmes should be further improved;
collaboration with other major public and private funders, including the pharmaceutical industry, needs to be strengthened and extended;

training needs to be promoted and developing countries' capacities stepped up;

cooperation with other major public and private partners, including the pharmaceutical industry, public-private partnerships such as Product Development Partnerships (PDPs), non-governmental organisations and foundations, and civil society needs to be strengthened and extended and respond to clear and transparent rules of governance;

synergies with European external policy actions should be developed, in particular with EU development assistance;

co-funding rules should be clarified and simplified;

monitoring tools need to be strengthened.


Amendment 2

Proposal for a decision
Recital 5 a (new)

Text proposed by the Commission

(5a) The Union is a major funder of research into poverty-related diseases and neglected infectious diseases. The
The Commission and Member States contribute nearly one quarter (22%) of relevant global investment by governments. The Union is also a major player in global health. For example, the Commission and Member States provide about half the financing for the Global Fund To Fight AIDS, Tuberculosis and Malaria.

Amendment 3

Proposal for a decision

Recital 7

Text proposed by the Commission

(7) Despite the considerable results and achievements of EDCTP1, poverty-related diseases still represent a major obstacle to the sustainable development of developing countries due to their social and economic burden, especially in sub-Saharan Africa. Effective, safe and affordable medical treatments still do not exist for most poverty-related diseases and investment in clinical research remains inadequate as conducting clinical trials is costly and the return on investment is limited due to market failure. Moreover, European research activities and programmes are still often fragmented and thus either subcritical in scale or overlapping, whereas research capacity and investment in developing countries are inadequate.

Amendment

(7) Despite the considerable results and achievements of EDCTP1, poverty-related diseases still represent a major obstacle to the sustainable development of developing countries due to their social and economic burden, especially in sub-Saharan Africa. Effective, safe, suitable, accessible and affordable medical treatments tailored to developing countries' specific circumstances still do not exist for most poverty-related diseases and investment in clinical research remains inadequate as conducting clinical trials is costly and the return on investment is limited due to market failure. It should be pointed out that only 10% of global research funding is allocated for the diseases which account for 90% of the world's pathologies. Moreover, European research activities and programmes are still often fragmented and thus either subcritical in scale or overlapping, whereas research capacity and investment in developing countries are inadequate.
Amendment 4

Proposal for a decision
Recital 11

Text proposed by the Commission

(11) The Commission presented a communication on 31 March 2010\textsuperscript{10} on the Union’s role in global health which calls for a more coordinated approach among Member States and across relevant policies to identify and jointly address shared global priorities for health research.

\textsuperscript{10} COM(2010) 128 final.

Amendment

(11) The Commission presented a communication on 31 March 2010\textsuperscript{10} on the Union’s role in global health which calls for a more coordinated approach among Member States and across relevant policies to identify and jointly address shared global priorities for health research. \textit{In that communication, the Commission also restates the need to promote equitable and universal coverage of quality health services plus effective and fair financing of research that benefits the health of all people.}

\textsuperscript{10} COM(2010) 128 final.

Amendment 5

Proposal for a decision
Recital 11 a (new)

Text proposed by the Commission

(11a) In 2010, in its "Council Conclusions on the EU’s role in global health", the Council called on the EU to promote effective and fair financing of research that benefits the health of all and ensures that innovations and interventions lead to affordable and accessible solutions. In particular, models that dissociate costs of R&D and the prices of medicines should be explored, including the opportunities for technology transfer to developing countries.

Amendment
Amendment 6
Proposal for a decision
Recital 12 a (new)

Text proposed by the Commission

(12a) In its 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 achievement of the MDG.

Amendment


Amendment 7
Proposal for a decision
Recital 13

Text proposed by the Commission

(13) In line with the objectives of Horizon 2020 Framework Programme, any Member State and any country associated to the Horizon 2020 Framework Programme should be entitled to participate in the EDCTP2 Programme.

Amendment

(13) In line with the objectives of Horizon 2020 Framework Programme, any Member State and any country associated to the Horizon 2020 Framework Programme should be entitled to participate in the EDCTP2 Programme. It should be ensured that projects receiving money via the Horizon 2020 Framework Programme are not in breach of international human rights law.
Amendment 8

Proposal for a decision
Recital 15

Text proposed by the Commission

(15) A ceiling should be established for the Union's participation in EDCTP2 for the duration of Horizon 2020 Framework Programme. Within that ceiling, the Union contribution should be equal to the initial contributions committed by the participating states in order to achieve a high leverage effect and ensure a stronger integration of participating states' programmes. That ceiling should also provide for matching the contributions from any other Member State or country associated to Horizon 2020 Framework Programme joining the EDCTP2 Programme during the Horizon 2020 Framework Programme.

Amendment

(15) A ceiling should be established for the Union's participation in EDCTP2 for the duration of Horizon 2020 Framework Programme. In that period, and within that ceiling, the Union contribution should be equal to the contributions of the states referred to in Article 1 of this Decision in order to achieve a high leverage effect and ensure a stronger integration of those states' programmes.

Amendment 9

Proposal for a decision
Recital 27 a (new)

Text proposed by the Commission

(27a) It is also important that the activities conducted under the EDCTP2 Programme should meet developing countries' needs and match the Union's global health commitments and that those activities should be consistent with the Union's development policy actions, as provided for by Article 208 of the Treaty on the Functioning of the European Union.

Amendment

(27a) It is also important that the activities conducted under the EDCTP2 Programme should meet developing countries' needs and match the Union's global health commitments and that those activities should be consistent with the Union's development policy actions, as provided for by Article 208 of the Treaty on the Functioning of the European Union.
Amendment 10
Proposal for a decision
Recital 28

Text proposed by the Commission

(28) Since the objectives of this Decision, namely 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 by accelerating the clinical development of effective, safe and affordable medical interventions for poverty-related diseases, cannot be sufficiently achieved by the Member States due to the lack of necessary critical mass to be achieved, both in human and financial terms, and can therefore, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary for that purpose.

Amendment

(28) Since the objectives of this Decision, namely to contribute to the reduction of the social and economic burden of poverty-related diseases and neglected diseases prioritising those with the greatest socioeconomic impact on the most vulnerable groups, in particular the children, in developing countries and in particular in sub-Saharan Africa by accelerating the clinical development of effective, safe, suitable, accessible and affordable medical interventions (diagnoses, drugs, treatments and vaccines) which are tailored to the specific needs and circumstances of the developing countries, cannot be sufficiently achieved by the Member States due to the lack of necessary critical mass to be achieved, both in human and financial terms, and can therefore, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Decision does not go beyond what is necessary for that purpose.

Amendment 11
Proposal for a decision
Article 2 – paragraph 1

Text proposed by the Commission

1. The maximum Union financial contribution, including EFTA appropriations, to the EDCTP2 Programme shall be EUR 683 million, as follows:

Amendment

1. The maximum Union financial contribution, including EFTA appropriations, to the EDCTP 2 Programme shall be EUR 683 million, to
(a) EUR 594 million to equal the contributions of participating states listed in Article 1.1;
(b) EUR 89 million to equal the contributions of any other Member State or any other country associated to Horizon 2020 Framework Programme participating in the EDCTP2 Programme in accordance with Article 1.2.

Amendment 12
Proposal for a decision
Annex I – paragraph 1

Text proposed by the Commission

(1) General Objective
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.

Amendment
(1) General Objective
EDCTP 2 shall contribute to the reduction of the social and economic burden of poverty related diseases and neglected diseases prioritising those with the greatest socioeconomic impact on the most vulnerable groups, in particular the children, in developing countries by accelerating the clinical development of effective, safe, suitable, accessible and affordable medical interventions (diagnoses, drugs, treatments and vaccines), which are tailored to the specific needs and circumstances of the developing countries, in partnership with these countries in sub-Saharan Africa.

Amendment 13
Proposal for a decision
Annex I – paragraph 2 – point a

Text proposed by the Commission

(a) an increased number of new or improved medical interventions for

Amendment
(a) an increased number of new or improved, accessible and appropriate
HIV/AIDS, tuberculosis, malaria and other poverty-related diseases, and by the end of the programme to have delivered at least one new medical intervention; to have issued at least 30 guidelines for improved or extended use of existing medical interventions; and to have progressed the clinical development of at least 20 candidate medical intervention.

**Amendment 14**

**Proposal for a decision**
**Annex I – paragraph 2 – point d**

*Text proposed by the Commission*

(d) extended international cooperation with other public and private funders;

*Amendment*

(d) extended international cooperation with other public and private partners - including NGO and foundations - and with other initiatives working to improve research into poverty related and neglected diseases, including for example product development partnerships, the World Health Organisation and its Consultative Expert Working Group (CEWG), and other programmes.

**Amendment 15**

**Proposal for a decision**
**Annex I – paragraph 2 – point e**

*Text proposed by the Commission*

(e) an increased impact due to effective cooperation with relevant European Union initiatives, including its development assistance.

*Amendment*

(e) an increased impact due to effective cooperation with relevant European Union initiatives, in particular its development assistance.
Amendment 16

Proposal for a decision
Annex I – paragraph 2 – point e a (new)

Text proposed by the Commission

Amendment

(ea) a higher profile for actions carried out under the EDCTP2 Programme at European and international level.

Amendment 17

Proposal for a decision
Annex I – point 3 – point a – paragraph 1

Text proposed by the Commission

Amendment

(a) Support clinical trials on new or improved medical interventions for poverty-related diseases through partnerships between European and developing countries, in particular sub-Saharan Africa:

(a) Support clinical trials on new or improved medical interventions for poverty-related and neglected diseases through partnerships between European and developing countries, in particular sub-Saharan Africa:

Amendment 18

Proposal for a decision
Annex I – point 3 – point a – paragraph 2

Text proposed by the Commission

Amendment

Target: increase the number of supported clinical trials to at least 150 compared to 88 under EDCTP1.

Target: increase the number of supported clinical trials, compared to 88 under EDCTP1, with a focus on clinical trials to develop new medical tools.

Amendment 19

Proposal for a decision
Annex I – point 3 – point a – paragraph 4
Target: Increase the number of peer-reviewed scientific articles published to at least 1000.

Amendment

Target: Increase the number of peer-reviewed scientific articles published.

Amendment 20
Proposal for a decision
Annex I – point 3 – point b – paragraph 2

Text proposed by the Commission
Target: sustain or increase the number of sub-Saharan African countries supported by the EDCTP2 to at least 30.

Amendment
Target: sustain or increase the number of sub-Saharan African countries supported by the EDCTP2.

Amendment 21
Proposal for a decision
Annex I – point 3 – point b – paragraph 3

Text proposed by the Commission
Target: increase the number of fellowships to sub-Saharan African researchers and MSc/PhD students to at least 600 compared to 400 under EDCTP1, with at least 90% of them continuing their research career in sub-Saharan Africa for at least one year after their fellowship.

Amendment
Target: increase the number of fellowships to sub-Saharan African researchers and MSc/PhD students from 400 under EDCTP1, strongly encouraging and supporting them to continue their research career in sub-Sahara Africa following their fellowship.

Amendment 22
Proposal for a decision
Annex I – point 3 – point b – paragraph 4

Text proposed by the Commission
Target: increase the number of capacity-building activities supported for

Amendment
Target: increase the number of capacity-building activities supported for
conducting clinical trials in sub-Saharan Africa to at least 150 compared to 74 under EDCTP1.

Amendment 23

Proposal for a decision
Annex I – paragraph 3 – point e – introductory part

Text proposed by the Commission
Amendment
(e) Establish cooperation and launch joint actions with other public and private funders.
(e) Establish cooperation and launch joint actions with other public and private partners.

Amendment 24

Proposal for a decision
Annex I – paragraph 3 – point f

Text proposed by the Commission
Amendment
(f) Establish cooperation and launch joint actions with Union, national and international development assistance initiatives in order to ensure complementarity and increase the impact of the results of EDCTP-funded activities.
(f) Establish cooperation and launch joint actions with Union, national and international development assistance initiatives in order to ensure complementarity and increase the impact of the results of EDCTP2-funded activities.

Amendment 25

Proposal for a decision
Annex I – paragraph 3 – point f a (new)

Text proposed by the Commission
Amendment
(fa) Raise the profile of actions carried out under the EDCTP2 Programme at European and global level, in particular in developing countries, by making use of political dialogue fora such as the ACP-EU Joint Parliamentary Assembly or EU-Africa Summits.
Amendment 26

Proposal for a decision
Annex II – point 1 – point a

Text proposed by the Commission

(a) promoting networking, coordination, alignment, cooperation and integration of national research programmes and activities on poverty-related infectious diseases at scientific, management and financial level;

Amendment

(a) promoting networking, coordination, alignment, open collaboration, cooperation and integration of national research programmes and activities on poverty-related and neglected diseases at scientific, management and financial level;

Justification

Limiting the scope to 'infectious' diseases means that the programme would not be able to fund research into other poverty-related and neglected diseases and conditions that may not be classed as 'infectious' but are nonetheless significant in developing counties, and also in need of R&D.

Amendment 27

Proposal for a decision
Annex II – paragraph 1 – point b

Text proposed by the Commission

(b) supporting clinical trial research and related activities on poverty-related diseases, in particular HIV/AIDS, malaria, tuberculosis and neglected infectious diseases;

Amendment

(b) supporting clinical trial research and related activities on poverty-related diseases, in particular HIV/AIDS, malaria and tuberculosis and neglected diseases prioritising those with the greatest socioeconomic impact on the most vulnerable groups;
Amendment 28

Proposal for a decision
Annex II – paragraph 1 – point c

Text proposed by the Commission

(c) fostering capacity development for clinical trials and related research in developing countries through grants for: career development of junior/senior fellows, promoting mobility, staff exchange grants, research training networks, strengthening ethics and regulatory bodies, mentoring and partnerships at individual or institutional level;

Amendment

c) fostering capacity development for clinical trials and related research in developing countries, in particular in sub-Saharan Africa, through grants for: career development of junior/senior fellows, promoting mobility, staff exchange grants, research training networks, strengthening ethics and regulatory bodies, mentoring and partnerships at individual or institutional level;

Amendment 29

Proposal for a decision
Annex II – paragraph 1 – point d

Text proposed by the Commission

(d) establishing cooperation and launching joint actions with other public and private funders;

Amendment

(d) establishing cooperation and launching joint actions with other public and private partners aiming at reinforcing national health systems and facilitating transfers of results to the population concerned;

Amendment 30

Proposal for a decision
Annex II – paragraph 1 – point e

Text proposed by the Commission

(e) assuring awareness, endorsement and acknowledgment of the EDCTP2 Programme and its activities through advocacy and communication.

Amendment

(e) 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, in particular in sub-Saharan Africa, but also at global level.
Amendment 31
Proposal for a decision
Annex II – point 3 – paragraph 1

Text proposed by the Commission

An annual report shall be provided by EDCTP2-IS, which shall give a detailed overview of the implementation of the EDCTP2 Programme. That overview shall provide information on each activity selected in accordance with the work plan, including indirect actions selected through calls for proposals managed by EDCTP-IS. Such information shall include a description of each activity, including indirect action, its budget, the value of the funding allocated to it if any, and its status.

Amendment

An annual report shall be provided by EDCTP2-IS, which shall give a detailed overview of the implementation of the EDCTP2 Programme. That overview shall provide information on each activity selected in accordance with the work plan, including indirect actions selected through calls for proposals managed by EDCTP-IS. Such information shall include a description of each activity, including indirect action, its budget, the value of the funding allocated to it if any, its status, and measures taken to ensure access to emerging products for populations in developing countries.

Amendment 32
Proposal for a decision
Annex II – point 3 – paragraph 2

Text proposed by the Commission

With regards to calls managed by EDCTP-IS, the annual report shall moreover include information on the number of projects submitted and selected for funding, the detailed use of the Union financial contribution, the distribution of national and other contributions, the types of participants, country statistics, brokerage events and dissemination activities.

Amendment

With regards to calls managed by EDCTP-IS, the annual report shall moreover include information on the number of projects submitted and selected for funding, the detailed use of the Union financial contribution, the distribution of national and other contributions, the types of participants, country statistics, brokerage events, dissemination activities, and measures taken to ensure access to emerging products.
Amendment 33

Proposal for a decision
Annex III – point 2 – paragraph 1

Text proposed by the Commission

2) The GA shall appoint a management board that shall supervise the secretariat of the EDCTP2-IS (hereinafter "SEC") established by the GA as the executive body of the EDCTP2 Programme.

Amendment

2) The GA shall appoint a management board. In so doing, the GA shall take due consideration of the contributions made by the participating states and ensure that the geographical distribution of the members of that board is balanced. The presence of at least one representative of sub-Saharan African countries shall be guaranteed.

The management board shall supervise the secretariat of the EDCTP2-IS (hereinafter "SEC") established by the GA as the executive body of the EDCTP2 Programme.
PROCEDURE

| Title | Participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme jointly undertaken by several Member States |
| Committee responsible | ITRE |
| Date announced in plenary | 10.9.2013 |
| Opinion by | DEVE |
| Date announced in plenary | 10.9.2013 |
| Rapporteur | Maurice Ponga |
| Date appointed | 11.11.2013 |
| Discussed in committee | 2.12.2013 |
| Date adopted | 18.12.2013 |
| Result of final vote | +: 20 |
| | --: 1 |
| | 0: 0 |
| Members present for the final vote | Ricardo Cortés Lastra, Véronique De Keyser, Catherine Grèze, Mikael Gustafsson, Filip Kaczmarek, Miguel Ángel Martínez Martínez, Gay Mitchell, Norbert Neuser, Bill Newton Dunn, Birgit Schnieber-Jaстрam, Michèle Striffler, Alf Svensson, Ivo Vajgl, Daniël van der Stoep, Anna Záborská |
| Substitute(s) present for the final vote | Kriton Arsenis, Emer Costello, Santiago Fisas Ayxela, Isabella Lövin |
| Substitute(s) under Rule 187(2) present for the final vote | Jolanta Emilia Hibner, Mary Honeyball |
## PROCEDURE

| Title | Participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme jointly undertaken by several Member States |
| Date submitted to Parliament | 10.7.2013 |
| Committee responsible | ITRE |
| Date announced in plenary | 10.9.2013 |
| Committee(s) asked for opinion(s) | DEVE | BUDG | ENVI |
| Not delivering opinions | BUDG | ENVI |
| Date of decision | 5.9.2013 | 5.9.2013 |
| Rapporteur(s) | Vicky Ford |
| Date appointed | 14.10.2013 |
| Discussed in committee | 9.1.2014 |
| Date adopted | 23.1.2014 |
| Result of final vote | +: 40 | -: 0 | 0: 0 |
| Members present for the final vote | Amelia Andersdotter, Bendt Bendtsen, Jan Březina, Maria Da Graça Carvalho, Giles Chichester, Jürgen Creutzmann, Pilar del Castillo Vera, Christian Ehler, Vicky Ford, Norbert Glante, Edit Herczog, Kent Johansson, Romana Jordan, Krišjānis Kariņš, Angelika Niebler, Jaroslav Paška, Aldo Patriciello, Vittorio Prodi, Miloslav Ransdorf, Herbert Reul, Teresa Riera Madurell, Michèlle Rivasi, Jens Rohde, Paul Rübig, Salvador Sedó i Alabart, Francisco Sosa Wagner, Konrad Szymański, Patrizia Toia, Evžen Tošenovský, Claude Turmes, Vladimir Urutchev, Kathleen Van Brempt |
| Substitute(s) present for the final vote | Maria Badia i Cutchet, Věra Flasarová, Elisabetta Gardini, Jolanta Emilía Hibner, Ivailo Kalfin, Vladko Todorov Panayotov, Lambert van Nistelrooij |
| Substitute(s) under Rule 187(2) present for the final vote | Jean-Paul Besset |
| Date tabled | 29.1.2014 |