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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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То:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe EU Africa global health partnership (Global Health EDCTP3)

Delegations will find attached document SWD(2021) 38 final - Part 1/9.

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PART 1/9

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document

Proposal for a Council Regulation establishing the Joint Undertakings under Horizon Europe

EU Africa global health partnership (Global Health EDCTP3)

{COM(2021) 87 final} - {SEC(2021) 100 final} - {SWD(2021) 37 final}

Executive Summary Sheet (Max 2 pages)

Impact assessment on a potential EU-Africa global health partnership (Global Health EDCTP3)

A. Need for action

What is the problem and why is it a problem at EU level?

Poverty-related and neglected infectious diseases remain the main cause of death, disability and ill health in many countries, with low- and middle-income countries having the highest burden. In addition, partly because of environmental and climate changes an increasing number of pathogens are emerging, or are reemerging with new characteristics, causing outbreaks such as COVID-19. These can spread rapidly around the globe causing huge human and economic suffering in many countries, including in Europe. Although there have been substantial developments in the field, especially in terms of new therapies, the rise in antimicrobial resistance is reducing the efficacy of existing treatments, and the available vaccines are not always sufficiently effective. New health technologies, such as precise diagnostic tests, therapeutic treatments and preventive vaccines are needed to alleviate the burden of infectious diseases and ensure that people live healthy and productive lives, especially in the most vulnerable and affected region, namely sub-Saharan Africa.

What should be achieved?

The EU-Africa global health partnership (Global Health EDCTP3) aims to reduce the burden of infectious diseases in sub-Saharan Africa and to help control emerging infectious diseases globally. This will be achieved by working in partnership with sub-Saharan African countries on a common research and innovation (R&I) strategic agenda to:

- advance the development of efficient new or improved health technologies;
- coordinate R&I efforts:
- strengthen R&I capacity for tackling infectious diseases; and
- increase R&I preparedness, early detection and control of (re-)emerging infectious diseases in sub-Saharan Africa and at global level.

What is the value added of action at the EU level (subsidiarity)?

Coordinated and coherent EU action will help to overcome fragmentation of R&I funding, attract a critical mass of organisations and the investment required to address this global health challenge, and facilitate collaboration and a strategic response to (re-)emerging infectious diseases. It will also increase the impact and cost-effectiveness of European action and investment. A partnership that can bring together the EU, European countries, African countries, other third countries and private global health funders will have a major impact at global level.

B. Solutions

What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?

To achieve these objectives, in addition to the traditional framework programme calls, the following four options were considered:

• a co-programmed European partnership;

- a co-funded European partnership;
- an institutionalised partnership under Article 185 of the EU Treaty;
- an institutionalised partnership under Article 187 of the Treaty.

An institutionalised partnership under Article 187 is the preferred option. This will allow countries other than EU Member States and Associate States, e.g. sub-Saharan Africa and other third countries, to be involved. The Article 187 option will also allow collaboration with industry and charitable foundations, which can help advance the common R&I agenda. This option has the highest capacity to leverage funds and to have the greatest impact.

What are different stakeholders' views? Who supports which option?

The stakeholders were unanimous in their preference for an institutionalised European partnership under either Article 185 or 187. The Article 187 option would bring together a wider range of public and private stakeholders, which would help ensure long-term commitment, financial certainty and an efficient organisational structure, leading to a higher potential impact.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise of main ones)?

Long-term and coherent support for infectious diseases R&I activities, networks, research capacities and knowledge exchange between institutions and European and sub-Saharan African countries will reduce the burden of disease in sub-Saharan Africa, and better control (re-)emerging infectious diseases in sub-Saharan Africa and at global level. With its focus on clinical research, the partnership's impact would take the form of effective health technologies that are ready for production, distribution and sale.

What are the costs of the preferred option (if any, otherwise of main ones)?

The cost of running the dedicated implementing structure would be less than \in 6 million per year, depending on the amount of the total budget. There would also be a \in 0.3 million one-off cost to set up the structure.

What are the impacts on SMEs and competitiveness?

SMEs will be able to participate in the partnership calls. The impact for them is not expected to differ from normal framework programme calls. However, significant opportunities - particularly in the digitalisation of health technologies - could lead to the growth of the SME sector in Europe and Africa.

Will there be significant impacts on national budgets and administrations?

The partnership will help streamline Member States' spending on infectious diseases R&I, including on international cooperation. It will also help sub-Saharan Africa countries plan the budgets of their national health research systems.

Will there be other significant impacts?

The partnership will support R&I in vaccines, diagnostics and medicines for infectious diseases that primarily affect low- and middle-income countries, helping to ensure healthy lives and the wellbeing of people of all ages (SDG3) and to end poverty in all its forms everywhere (SDG1).

Proportionality?

The preferred option provides all the elements to achieve the objectives and does not go beyond what is necessary to solve the problem.

D. Follow-up

When will the policy be reviewed?

The policy will be reviewed in line with the timescale set out in the Horizon Europe Regulation and with the requirements to be laid down in the relevant basic act.