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ANNEX 2

of the Commission Implementing Decision on the financing of the multiannual action plan in favour of Sub-Saharan Africa for 2021

Action document for Accelerating the COVID-19 response and strengthening health systems through digital health tools

ANNUAL PLAN
This document constitutes the annual work programme in the sense of Article 110(2) of the Financial Regulation, and action plan in the sense of Article 23 (2) of NDICI-Global Europe Regulation.

1. SYNOPSIS

1.1. Action Summary Table

1. Title **CRIS/OPSYS business reference** **Basic Act**	**Accelerating the COVID-19 response and strengthening health systems through digital health tools**. CRIS number: 2021/043-462 Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe).
2. Team Europe Initiative	Yes, this action will support the Team Europe Initiative (TEI) on Digital Health. The Commission is designing this TEI jointly with EU Member States (EU MS) – some of them part of the Digital4Ddevelopment Hub (D4D Hub), namely Germany, France and Belgium. The European Investment Bank (Member of the D4D hub) will also take part in the implementation of this TEI. Spain, Italy and Sweden have expressed interest. Germany and Sweden have already committed to a financial contribution to COVID-19 digital health tools, including in the Global Trust Repository to fight counterfeit medicines. Other EU Member States are also considering financial contributions to these tools. A joint budget will be provided once the TEI is established
3. Zone benefiting from the action	The action shall be carried out in the sub-Saharan Africa region.
4. Programming document	MULTI-ANNUAL INDICATIVE PROGRAMME FOR SUB-SAHARAN AFRICA 2021-2027
5. Link with relevant MIP(s) objectives/expected results	**Priority Area 1: Human development: Health** Specific Objective 1: Strengthen health systems and health outcomes, contributing to universal health coverage, with greater coherence across African regions, thereby substantiating the EU-Africa partnership in health, and the external dimension of the new European Health Union. Expected Result 1.1: The African architecture for health security and pandemic preparedness is strengthened sustainably. Expected Result 1.2: African pharmaceutical systems and regional manufacturing capacity for vaccines and other medical products and technologies are strengthened. **Priority Area 4: Digital and Science, Technology and Innovation: Digital transformation**

	Specific Objective 1: Support an inclusive and human-centric Digital transformation in Africa. Result 1.1: Secure, human-centric and harmonised digital standards, legal and regulatory frameworks are promoted at regional/continental levels.
PRIORITY AREAS AND SECTOR INFORMATION	
6. Priority Area(s), sectors	DAC codes: 12250 (Infectious disease control) 22040 (ICT)
7. Sustainable Development Goals (SDGs)	Main SDG (1 only): SDG 3 (health) Other significant SDGs: SDG 8 (jobs and growth), SDG 9 (Industry), SDG 17 (Partnerships, trade)
8 a) DAC code(s) [1]	12250 Basic Health - 50% 22040 Information and communication technology (ICT) - 50%
8 b) Main Delivery Channel @	DAC 40000 Multilateral organisations DAC 60000 Private sector institution
9. Targets[2]	☐Migration ☐ Climate ☒ Social inclusion and Human Development ☐ Gender ☐ Biodiversity ☐ Education ☐ Human Rights, Democracy and Governance[3]

10. Markers [4] (from DAC form)

General policy objective @	**Not targeted**	**Significant objective**	**Principal objective**
Participation development/good governance	☐	☐	☒
Aid to environment @	☒	☐	☐
Gender equality and women's and girl's empowerment	☒	☐	☐
Trade development	☐	☒	☐
Reproductive, maternal, new-born and child health	☒	☐	☐
Disaster Risk Reduction @	☐	☒	☐
Inclusion of persons with Disabilities @	☒	☐	☐
Nutrition @	☒	☐	☐

[1] DAC sectors (codes and descriptions) are indicated in the first and fourth columns of the tab 'purpose codes' in the following document: http://www.oecd.org/dac/financing-sustainable-development/development-financestandards/dacandcrscodelists.htm

[2] Actual contribution to targets will be confirmed ex-post based on a standardised methodology.

[3] Thematic target for geographic programmes (at least 15%) in delegated act.

[4] For guidance, see https://www.oecd.org/development/financing-sustainable-development/development-finance-standards/ (go to "Data collection and resources for reporters", select Addendum 2, annexes 18 (policy) and 19 (Rio) of the reporting directive).
If an action is marked in the DAC form as contributing to one of the general policy objectives or to RIO principles as a principal objective or a significant objective, then this should be reflected in the logframe matrix (in the results chain and/or indicators).

	RIO Convention markers	**Not targeted**	**Significant objective**	**Principal objective**
	Biological diversity @	☒	☐	☐
	Combat desertification @	☒	☐	☐
	Climate change mitigation @	☒	☐	☐
	Climate change adaptation @	☒	☐	☐
11. Internal markers[5] and Tags[6]:	**Policy objectives**	**Not targeted**	**Significant objective**	**Principal objective**
	Digitalisation @	☐	☐	☒
	Tags: digital connectivity		☒	☐
	digital governance		☒	☐
	digital entrepreneurship		☐	☐
	job creation		☐	☐
	digital skills/literacy		☐	☐
	digital services		☒	☐
	Connectivity @	☐	☒	☐
	Tags: transport		☐	☐
	people2people		☐	☐
	energy		☐	☐
	digital connectivity		☒	☐
	Migration @ (methodology for tagging under development)	☒	☐	☐
	Reduction of Inequalities (methodology for marker and tagging under development)	☒	☐	☐
	Covid-19	☐	☐	☒
BUDGET INFORMATION				
12. Amounts concerned	Budget lines: • BGUE-B2021-14.020120-C1-INTPA (West Africa) – EUR 6 800 000 (40%) • BGUE-B2021-14.020121-C1-INTPA (East and Central Africa) – EUR 6 630 000 (39%) • BGUE-B2021-14.020122-C1-INTPA (Southern Africa and Indian Ocean) – EUR 3 570 000 (21%) Total estimated cost: EUR 17 000 000 Total amount of EU budget contribution EUR 17 000 000			
MANAGEMENT AND IMPLEMENTATION				
13. Type of financing[7]	**Direct management** through procurement			

[5] The internal markers have been created to report on the implementation of the Commission's own policy priorities in areas where no DAC reporting tool is available. For the sake of consistency and comparability, the methodology is equivalent to the DAC markers, with three possible positions (main target, significant target, not targeted)
[6] Methodology for additional tagging providing granularity on internal markers is under development.
[7] Art. 27 NDICI

	Indirect management with an international organisation.

1.2. Summary of the Action

The Action aims to support the COVID-19 vaccination efforts, strengthen health systems in sub-Saharan Africa through the deployment of digital health tools and relaunch the mobility and trade exchanges in the region and across the EU and the African Union (AU). This action will complement EU's Global Response to COVID-19, including its commitments to Vaccine pillar of the Access to Covid-19 Tools Accelerator (ACT-A) and to local manufacturing in Africa while it will also promote EU Standards and strengthen the external dimension of the EU's digital agenda. The action is envisaged to:

1. Support the external dimension of the EU Digital COVID Certificate (DCC). *An increasing number of requests from partner countries in Africa is being received for the deployment and scale up of a system that can authenticate COVID-19 vaccination, recovery and test certificate status and that is interoperable with pre-existing tools at regional and at national level. In the absence of such tool at a global level, the EU faces an unprecedented window of opportunity to be seized for the scale-up and deployment of the EU DCC in Africa, while increasing EU visibility and promoting EU standards, policies and priorities. This action will support the establishment of country platforms and facilitate the request and establishments of adequacy decisions with the EU DCC. A continental agreement with the Africa Centre for Disease Control for a reciprocal Trust Interchange system will be established through this action to pool the adequacy decision request from partner countries and sub-regions in Africa through a single harmonised channel.*

2. ***Upscale digital health tools for vaccine counterfeit detection***. *The scarcity of COVID-19 vaccines has led to the proliferation of counterfeit COVID-19 vaccines. Through this action, we propose to support the digitalisation of counterfeit medicine detection systems, through country/regional deployment of a 'Global Trust Repository for authenticity verification'. This tool, currently under development by UN agencies consists of two components: a) a global database centralising all vaccine serial numbers, and b) country systems to scan and verify the vaccines authenticity as they are administered. This action will aim to support the second component, covering the detection of counterfeit COVID-19 vaccines in the short term and in view of expanding the scope to detect a broader range of counterfeit medicines and other health products in the long term, thus supporting strengthening health systems in the region.*

2. RATIONALE

2.1. Context

The COVID-19 pandemic has exposed several global challenges and new important political priorities have emerged in 2020, as as expressed in the Joint Communication on the global EU response to COVID-19 and the Communication establishing a European Health Union. With disruptions to essential health services, to pharmaceutical supply chains and the availability of essential health products, the strain on health care workers, disruptions to mobility across continents and its economic impact, COVID-19 has transformed health into a global, European and African priority.

The pandemic in the presence of other endemic diseases (such as Ebola, TB, Malaria or HIV) has once more underlined the urgent need to strengthen Africa's public health systems as prerequisite to a sustainable development. At continental level, the AU has long had political traction and convening power, and it now also has, with the Africa Centres for Disease Control and Prevention (and the new African Medicines Agency), a vision for a new public health order in Africa and growing operational capacity to advance this vision, coordinate continental and sub-regional responses and turn health systems strengthening (HSS), local manufacturing of vaccines and therapeutics, health workforce development, into a pillar of the EU-Africa partnership.

The Commission digital strategy has consistently maintained health as a priority. The 2030 Digital Compass Communication identifies health as a key ecosystem for digital transformation and recalls the window of opportunity brought by the COVID-19 pandemic, showing the "…potential and paving the way for generalised use of innovative telemedicine […]. Digital technologies can empower citizens to monitor their health status […] prevent non-communicable diseases, and bring efficiency to health and care providers and health systems'.

The digital ambitions for the EU partnership with Africa highlight health as a priority. The Joint Communication to the European Parliament and the Council "Towards a Comprehensive Strategy With Africa", emphasizes that access to safe and affordable digital services need to be ensured for all, including improving access to health services in remote areas and by facilitating diagnostics and treatments. The Digital Transformation Strategy For Africa (2020-2030) and the New Africa-Europe Digital Economy Partnership report, both highlight the potential of digital investments in Africa to transform and improve access to quality basic services, including healthcare.
With significant commitments to the purchase of vaccines through the COVAX (COVID-19 Vaccines Global Access) Facility, the EU is one of the lead donor and strong advocate for equitable vaccine access. Ensuring equity and efficiency of vaccine distribution and certification of vaccinated citizens are two of the most pressing needs.

The EU has developed the EU Digital COVID Certificate with the aim of facilitating free movement inside the EU. The EU Digital COVID Certificate covers Covid-19 vaccination, test and recovery. It is a tool allowing for the gradual lifting of travel restrictions and the resumption of safe free movement within the EU ahead of the summer period and, as such, aims to contribute to overall recovery.

This action is in line with the Union's and Member States' priorities and commitments to the COVAX Facility. Similarly, it will build upon the regional action for pharmaceutical systems in Africa, which aims to ramp-up local production and ensure quality of health products in Africa. The action contributes to two priority area of the Multi-Annual Indicative Programme for Sub-Saharan Africa (SSA)RIP 2021-2027: human development (Priority Area 1) and digitalisation (Priority Area 4) and aims to support and accelerate the COVID-19 response through digital health tools in the short term and to strengthen health systems in the long term. In a context where a multiplicity of digital tools is under development for the deployment of COVID-19 digital health tools, and the objectives to scale-up vaccination to 60% by mid-2022 globally, it will be important that the EU urgently invests and promotes digital health tools following the EU values and standards of inclusivity, scalability, interoperability, data protection and privacy, equality and equity, non-discrimination, cybersecurity and trust with strong political support. Collaboration on this topic with EU Member States is being explored through a Global Team Europe initiative.

This action is in line with the 2030 Digital Compass Communication, the Joint Communication to the European Parliament and the Council "Towards a Comprehensive Strategy with Africa", as well as with the Digital Transformation Strategy for Africa (2020-2030), which all identify health as a key ecosystem of digitalisation.

Finally, this action will enhance both EC's commitment to sustainable and human-centred digitalisation and to bringing the pandemic to an end. Beyond vaccine purchase and sharing, this action extends the ongoing EC's action by supporting the vaccination chain continuum through digital tools and includes tracing vaccine doses as well as digital certification of vaccination status. As the first operational tool at regional scale, the EU digital COVID Certificate has the potential of being the main global vaccine certificate, which would send a strong signal of the EU's commitment to global health and digitalisation. In the same way, the European Medicines Verification Organisation (EMVO) has been used as a model to the set-up of the Global Trust Repository for authenticity verification. An EU commitment to the GTR would promote the EU's engagement to fight counterfeit medicines and allow to shape this nascent tool from inside through the integration of its steering committee. This would be key to promote and upscale existing European structures and networks (MEDICRIME, EMVO, MHRA, EMA…[8]) from the onset of the tool development.

2.2. Problem Analysis

With over 200 million EU vaccines to be shared by the end of 2021 and more than EUR 3 billion Team Europe pledge to COVAX , the EU is one of the lead donor and strong advocate for equitable vaccine access. However, the high inequalities raising from the current distribution of COVID-19 vaccines and other COVID technologies such as

8 MEDICRIME (Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health), EMVO (European Medicines Verification Organisation), MHRA (Medicines and Healthcare products Regulatory Agency), EMA (European Medicines Agency)

diagnostics and therapeutics widens social inequities and disparities, and the reversal of gains toward gender equality, going against the EU's value of equity and leading to unintended consequences to be urgently tackled.

Cross-border travel are depending on tests or vaccine certificates, which increases inequalities, both in health and free movement. The current status of non-recognition of the EU DCC and certificates produced in the African region risks to create a significant obstacle for the mobility of people, goods and services, with the consequence, that the EU's investment in to the economic strengthening of sub-Saharan Africa would be severely jeopardized. Therefore, the current roll-out of the EU Digital Green Certificate within Europe calls for the development of a strong international dimension, particularly with Africa.

For instance, the scarcity of vaccine doses leads to an increased reporting of counterfeit COVID-19 vaccines. The 2020 report from the Organisation for Economic Co-operation and Development and the European Union Intellectual Property Office on 'Trade in Counterfeit Pharmaceutical Products' finding that trade in falsified medicine reached USD 4.4 billion in 2016, threatening public health and safety**.** Africa with the highest prevalence (18.7 per cent) of falsified and substandard medicines is particularly at risk from counterfeit medical supplies and fake coronavirus 'cures'. The Global Trust Repository (GTR), promoted by international donors and UN organisations is currently developed to be a universal tool based on a unified standard. The GTR aims at enabling participating countries to manage the risk of falsified COVID 19 vaccines in their national supply chains, while setting the foundation for the establishment of national traceability systems in the long term. Thus, with the help of the GTR, countries can assess and use for verifying the validity of COVID-19 vaccines. The wider significance of the GTR and rationale for the EU to support the availability of this tool is that in future apart from tracing initially data from COVID-19 vaccine manufacturers, all medicines manufacturers can be traced and thus the quality of medicines. The EU in pursuing its strategic partnership with Africa (and also with other third countries) will need to include support to the GTR, to ensure no one is left behind.

In comparison to the substantial commitments to COVAX or to local production capacity, relatively modest financial commitments in digital health tools can enhance the result of the above mentioned programs and strengthen the Commissions' engagement of leaving no one behind.

Identification of main stakeholders and corresponding institutional and/or organisational issues (mandates, potential roles, and capacities) to be covered by the action:

For the support to the Digital COVID Certificate external action the main stakeholders will be the European Commission (EC), the African Union, partner countries and organisations responsible of the operationalisation of the certificate. Collaboration on this topic with EU Member States is ongoing through a Team Europe initiative, jointly set-up by the EC and Member States (through the D4D Hub – Digitalisation for Development Hub).
For the Global Trust Repository for authenticity verification, the main stakeholders will involve the EC, Member States (Sweden), potential participation, through the steering committee, of the European Investment Bank, the World Bank Group, UNICEF (United Nations Children's Fund), the African Union, Africa CDC (Centre for Disease Control and Prevention), Regional Economic Communities (REC), the private sector.

This action will be coordinated with other global donors programs through the 'Digital Donor Coordination for COVID' group (Global Fund, Gavi, Bill and Melinda Gates Foundation, Deutsche Gesellschaft für Internationale Zusammen arbeit(GIZ), Foreign Commonwealth and Development Office, United Kingdom (FCDO), United States Agency for International Development (USAID) World Health Organisation (WHO0, United Nations Children's Fund (UNICEF).

3. DESCRIPTION OF THE ACTION

3. Objectives and Expected Outputs

The Overall Objective (Impact) of this action is to contribute to strengthening African health systems through the availability of safe and quality COVID-19 tools.

The Specific Objectives [SO] (Outcomes) of this action are to:

1. External dimension of the DCC: Enhance certification of COVID-19 vaccination, testing and recovery status that is interoperable across regional and national systems in the AU and the EU;

2. Global Trust Repository: Strengthen authenticity and verification of non-counterfeit health products in Africa.

The Direct Outputs [DO] are:

Contributing to Outcome 1:

1.1 Enhanced capacity of EU compliant DCC at national level in Africa

1.2 Strengthened capacity for EU compliant national/sub-regional systems across continental Africa harmonised

Contributing to Outcome 2:

2.1. Enhanced capacity of the Global Trust Repository for authenticity verification to detect counterfeit COVID-19 vaccines

2.2 Capacity for detection of counterfeit medicines and other health products in the long term at country/regional level enhanced

3.1. Indicative Activities

Activities related to Output 1.1

- Conduct gender-sensitive assessment of pre-existing national systems recording data on vaccination, testing and recovery from covid-19 status.
- Funding technical assistance for the deployment of EU DCC systems at national level.
- Funding establishment of EU DCC system at multi-country level, as necessary.

Activities related to Output 1.2

- Conduct gender-sensitive assessment of harmonisation needs for pre-existing and new national systems recording data on vaccination, testing and recovery status at sub-regional/regional level.
- Establish close coordination mechanisms with Africa CDC to deploy EU compliant interoperable DCC system at sub-regional/regional level

Activities related to Output 1.3

- Establishment of Reciprocal Trust Exchange mechanism between EU and AU

Activities related to Output 2.1:

- Establish close coordination mechanism with GTR Steering Committee
- Conduct gender-sensitive assessment of pre-existing national logistics management and information (LMIS) systems

Activities related to Output 2.2:

- Conduct assessment of needs and pre-existing systems for detection of counterfeit medicines and other health products
- Establish coordination mechanism with the COVID-19 Digital Health Centre for Excellence (DICE) for the provision of technical assistance
- Support establishment of national system for detection of counterfeit medicines and other health products
- Support interoperability of pre-existing systems with GTR at multi-country level.
- The commitment of the EU's contribution to the Team Europe Initiative foreseen under this annual action plan will be complemented by other contributions from Team Europe partners. It is subject to the formal confirmation of each respective partners' meaningful contribution as early as possible. In the event that the TEIs and/or these contributions do not materialise the EU action may continue outside a TEI framework.

3.2. Mainstreaming

Mainstreaming in AAP is very general and provided possibly before the mandatory analysis at action level are realised. This sections is based on the mainstreaming annex. We suggest to keep it.

Environmental Protection & Climate Change

Outcomes of the SEA screening –no further action was required.

Outcomes of the EIA (Environmental Impact Assessment) screening Category C (no need for further assessment).

Outcome of the CRA (Climate Risk Assessment) screening No or low risk (no need for further assessment).

Gender equality and empowerment of women and girls

This action is labelled as G0 as this action is oriented mainly to create or improve online platforms. However, the action will still be gender sensitive, to ensure it avoids worsening gender differences, with the aim to exclude potential biases from digital design. Assessments will be gender sensitive and integrate the Human Rights Based Approach to ensure at least a "do not harm approach".

Human Rights

This action will systematically, in particular through gender sensitive and from a human based approach assessment, seek to contribute to reduce the divide across societal categories and geographic dimensions. It will provide new tools for inclusive and equitable growth and overall improvement of human rights, including for women, youth and people with disabilities. Right to privacy, cyber-security should also be upheld. EU Standards (GDPR) will be followed.

Disability

As per OECD Disability DAC codes identified in section 1.1, this action is labelled as D0 (not targeted).

Democracy

Attention will be paid to ensure democratic values are upheld.

Conflict sensitivity, peace and resilience

Not addressed by the action.

Disaster Risk Reduction

The action directly contributes to minimising hazards of falsified and counterfeit medicines and spread of infectious disease, thus reducing the risk of outbreaks, epidemics and antimicrobial resistance.

Other considerations if relevant

N/A

3.3. Risks and Lessons Learnt

Category	**Risks**	**Likelihood (High/ Medium/ Low)**	**Impact (High/ Medium/ Low)**	**Mitigating measures**
Project management: Regional approach related to the DCC	Diversity of country regulations not harmonized at country/regional level	**low**	**medium**	Countries need to comply to the EU DCC standards and regulations. Adequacy decision will not be granted if standards are not align.

Inequalities: Exclusively digitised vaccine registration systems could risk perpetuating exclusion of vulnerable populations	Gaps in digital literacy and those with limited access to digital infrastructure or smartphones are not able to obtain their DCC	**medium**	**medium**	The DCC will include a paper-based option that will enable vulnerable populations with limited access to digital resources to obtain their certificate.
EU standards: Vaccine acceptance by EU vis a vis vaccines used in Africa	Vaccines applied in SSA not being recognized by EU	**medium**	**medium**	Issues in mutual recognition of vaccines used in Africa will be addressed and solved between stakeholders including EU institutions (EMA, ECDC)
EU Standards: Verification certificate and trust repository	Setting up EU repository risking non-compliance with third country platforms	**low**	**medium**	Through negotiations in the GTR Steering Committee and other for a and with the involvement of EU institutions, non-compliance issues will be resolved

Lessons Learnt:

The EU Digital Covid Certificate (EU DCC) is ongoing since the first half of 2021 and the lessons to be learned related to the EU DCC may address the need of a necessary close cooperation between the EU and third countries, several of whom have already approached the EU for the validation of their vaccination certificates. It will be imperative to explore modalities of a standardized and mutually recognized EU DCC to enhance global public health, economic recovery and free movement of people in the post Covid era.

Vaccines against COVID-19 have been introduced not even a year ago, and lessons learned are slowly emerging and lessons to be learned in future are becoming very clear related to the production of counterfeit medicines. In March 2021, the World Health Organisation issued a strong warning against counterfeit vaccines sold on the dark web and urged people to buy vaccines only from government-run programs, as "any vaccine outside these programs may be substandard or falsified, with the potential to cause serious harm,"[9] As the COVID vaccine market is worth at least USD 150 billion, countries all over the world are reporting the sale of fake, or misleadingly labelled, vaccines. Counterfeit COVID vaccines are part of the rapidly increasing worldwide trade in fake medicines that poses a grave threat to health. The highest risk – according to UNICEF[10] - for the distribution of counterfeit vaccines is in low- and middle-income countries national supply chains, where governance structures and traceability systems are non-existent or not fully mature, and tools and technical capacity to ensure good practices in manufacturing, quality control and monitoring of distribution chains is limited.

In December 2020 the OECD published an editorial, highlighting that even before the COVID-19 pandemic, "… global illicit trade was already booming from an array of trafficking and smuggling crimes. COVID-19 has accelerated illicit trade across the Internet on social media, e-commerce platforms, and online marketplaces, alarming law enforcement and broader communities in many parts of the world." [11]

3.4. The Intervention Logic

[9] https://www.cnbc.com/2021/03/26/who-warns-against-sales-of-counterfeit-covid-vaccines-on-the-dark-web.html
[10] file:///C:/Users/Mein%20PC/Downloads/Annex%20B_Global%20Trust%20Repository%20-%20ToR%20(1).pdf
[11] https://www.oecd.org/gov/illicit-trade/summary-note-covid-19-vaccine-and-the-threat-of-illicit-trade.pdf

The underlying intervention logic for this action is confirming the EU commitment to tackle the COVID-19 pandemic and strengthen the health systems in sub-Saharan Africa, with actions ranging from securing and sharing vaccine doses, detecting counterfeit vaccines to inclusively registering vaccine, test or recovery status of citizen through an open source global public good. This action constitutes a first concrete deliverable on the 4th pillar of external dimension of the Digital Compass communication, through the Digital Health Team Europe Initiative, with a joint contribution to the Global Trust repository for authenticity verification, together with Sweden and a potential contribution of the EIB.

The Digital COVID Certificate will provide the unique opportunity and strong signal of the EU's engagement in digital health at global level. It will allow to set EU based standards and tools as global standards in all partner countries, while at the same time ensuring technical assistance and interoperability to countries which may choose different verification certificates. Thus, this action will support the operationalization of the external dimension of the EU DCC. It will also enhance the capacity of countries in sub-Saharan Africa to deploy EU compliant DCC at national level. By this scale-up of the EU DCC and enhancing its interoperability in Sub-Saharan Africa will also enable the political, economic and cultural cooperation between the EU and the AU to gain a sustainable momentum.

Through the provision of technical assistance and financial support to the establishment of EU compliant country platforms and certification, this action will enhance the establishment of COVID status certification in Africa, increase and facilitate the interoperability of the tools with the EU DCC, hence re-establish mobility and trade across countries in Africa and between the EU and the AU, whilst limiting cross-border transmission of the virus. Moreover, this action could be a first building block for the innovative use of digital technologies for health thus contributing to the health systems digitalisation and strengthening - a priority under the EU – Africa partnership.

The Global Trust Repository for authenticity verification (GTR), based on the European Medicine Verification Organisation standards, will support a system for the detection of counterfeit vaccines, both for COVID-19 vaccine deployment in the short term and for the European Union's goal to increase local production and ensure quality of medical products in the medium to long term. This action will enhance the capacity of the GTR and expand its capacity for the detection of vaccines and also other health products at multi-country/regional levels.

Through the provision of capacity and financial support for the development of country platforms for the detection of counterfeit medicines, this action will enhance the connectivity and interoperability of national detection systems with the global trust repository. The action will contribute to the digital transformation of healthcare, to the regulatory system strengthening and will be synergistic with the actions facilitating health products manufacturing and effective use.

3.5. Logical Framework Matrix

At action level, the indicative logframe should have a maximum of 10 expected results (Impact/Outcome(s)/Output(s)).
It constitutes the basis for the monitoring, reporting and evaluation of the intervention.
On the basis of this logframe matrix, a more detailed logframe (or several) may be developed at contracting stage. In case baselines and targets are not available for the action, they should be informed for each indicator at signature of the contract(s) linked to this AD, or in the first progress report at the latest. New columns may be added to set intermediary targets (milestones) for the Output and Outcome indicators whenever it is relevant.

- At inception, the first progress report should include the complete logframe (e.g. including baselines/targets).
- Progress reports should provide an updated logframe with current values for each indicator.
- The final report should enclose the logframe with baseline and final values for each indicator.

The indicative logical framework matrix may evolve during the lifetime of the action depending on the different implementation modalities of this action.
The activities, the expected Outputs and related indicators, targets and baselines included in the logframe matrix may be updated during the implementation of the action, no amendment being required to the Financing Decision.

Results	Results chain (@): Main expected results (maximum 10)	Indicators (@): (at least one indicator per expected result)	Baselines (values and years)	Targets (values and years)	Sources of data	Assumptions
Impact	African health systems are strengthened through the availability of safe and quality COVID-19 tools.	Incidence of COVID-19 infections in Sub-Saharan African countries (average per region) (gender disaggregated)	1 - TBD	1 – X decreased COVID-19 incidence by x% over 2 years	1 Reports from Africa CDC 'ACDC)	*Not applicable*
Outcome 1	1.1 External dimension of the Digital COVID-19 Certificate (DCC): The certification of COVID-19 vaccination, testing and recovery status that is interoperable across regional and national systems in the AU and the EU is enhanced	1.1 Number of countries with an interoperable DCC 1.2 Number of DCC's scanned in EU and AU countries participating 1..3 Number of national DCC platforms connected to African Union Digital Certificate (AU DC 1.4 Level of functionality of Coordination mechanism with Africa CDC established	1.1- 0 1.2 - 0 1.3-0 1.4 -0	1.1 – X countries with DCC deployed (tbd during inception) 1.2 TBD during Inception, disaggregated by sex 1.3 X national DCC platforms connected to AU DCC 1.4 X agreements/Memoranda of Understanding (MoUs) with ACDC	1.1 Country progress reports 1.2 Internal commission data through the EU DCC Functional Mail Box 1.3 Reports from ACDC 1.4 Country progress reports	Countries and regions are prepared to adjust their laws and regulations to enable the adaptation process of respective platforms to the DCC and report regularly on the roll-out of the programme.
Outcome 2	2. The Global Trust Repository: Authenticity and verification of non-counterfeit health products in Africa are strengthened.	2.1 Number of additional countries with established detection system from the onset of the action 2.2 Number of countries connected to the GTR 2.3 Proportion of non-counterfeit medical products in partner countries	2.1 - 0 2.2 – 0 2.3 - 0	2.1 X countries established a national detection system 2.2 X countries connected to the GTR 2.3 increase of X % of non-falsified medical products within 2 yrs	2.1 Annual reports from implementing partner 2.2 Annual reports from implementing partner 2.3 Reports from national medicines agencies	Access to all health products is ensured and countries and regional bodies are closely cooperating and coordinating and sharing their relevant data.

Output 1 related to Outcome 1	1.1 Enhanced capacity for deployment of EU compliant DCC and gender-sensitive at national level in Africa 1.2 Strengthened capacity for harmonisation and interoperability of national/sub-regional systems across continental Africa with EU DCC 1.3 Adequacy decisions for EU compliance as necessary are established 1.4 Level of functionality of Coordination mechanism with Africa CDC established	1.1.1 Number of national DCC platforms established/operational attributed to this action (gender-sensitive) 1.2.1. Number of countries receiving technical assistance for deployment of DCC at national level attributed to this action 1.3.1 Number of EU adequacy decisions drafted with support of the EU-funded intervention 1.4.1 Approved coordination mechanism by the EU and the AU	1.1.1 - 0 1.2.1 - 0 1.3.1 – 0 1.4.1 – Draft proposal	1.1.1 X national DCC platforms funded 1.2.1 X countries connected to the EU Gateway 1.3.1 – X positive adequacy decisions 1.4.1 Coordination mechanism with Africa CDC established	1.1.1 Bi-annual report of implementing partner 1.2.1 Internal EC data/ implementing partner reports 1.3.1- Internal EC data 1.4 Internal EC/ACDC data	National institutions have adjusted their regulatory frameworks to deploy EU compliant DCC and have upgraded their institutional capacities to ensure harmonization and interoperability. Countries and sub-regional systems are closely cooperating.
Output 1 related to Outcome 2	2.1 The capacity of the 'Global Trust Repository (GTR) for authenticity verification' to detect counterfeit COVID-19 vaccines that is interoperable is enhanced. 2.2 The capacity for the detection of counterfeit medicines and other health products (serving the needs of both girls/women and boys/men) in the long term at multi-country/regional levels is enhanced.	2.1.1 Number of countries receiving technical assistance for deployment of GTR 2.2.1 The number of counterfeit health products (vaccines, medicines) in partners countries detected.	2.1.1 X countries receiving technical assistance for deployment of GTR 2.2.1 - TBD	2.1.1 - TBD in Inception 2.2.1 -TBD in Inception	2.2.1 – Country progress reports, Reports from implementing partner 2.2.2 – Country progress reports, Reports from ACDC	Countries and regions have adapted their regulatory systems and are willing to share data on counterfeit products. Countries and regions have strengthened their medicine regulatory agencies/institutions to enable comprehensive medical product registration and reporting

4. IMPLEMENTATION ARRANGEMENTS

4.1. Financing Agreement

In order to implement this action, it is not envisaged to conclude a financing agreement.

4.2. Indicative Implementation Period

The indicative operational implementation period of this action, during which the activities described in section 3 will be carried out and the corresponding contracts and agreements implemented, is 72 months from the date of the adoption by the Commission of this Financing Decision. Extensions of the implementation period may be agreed by the Commission's responsible authorising officer by amending this Financing Decision and the relevant contracts and agreements.

4.3. Implementation of the Budget Support component

N/A

4.4. Implementation Modalities [applicable for Project modality or for complementary support to a BS]

The Commission will ensure that the EU appropriate rules and procedures for providing financing to third parties are respected, including review procedures, where appropriate, and compliance of the action with EU restrictive measures[12].

4.4.1. Direct Management (Procurement)

Service contract:

(a) Purpose of the service contract(s): The service contract will contribute to the deployment of the EU DCC and ensure the external dimension of the tool is strengthened

The contract will contribute to achieving the set-up of COVID certificate in partner countries, ensure interoperability of pre-existing country systems in Africa where possible and streamline the equivalence decision requests through regional channels.

(b) Type of applicants targeted

The applicants targeted are ICT companies with experience in the deployment of digital certificates and trust gateways.

4.4.2. Indirect Management with an international organisation.

A part of this action (Specific Objective 2: Global Trust Repository) may be implemented in indirect management with an International Organisation, which will be selected by the Commission's services using the following criteria: full five pillar assessment, regional outreach, operational capacity to deliver the project at regional level with relevant health and ICT competences, engagement in the fight against counterfeit medicines. The implementation by this entity entails the completion of assessment of needs and pre-existing systems for detection of counterfeit medicines and other health product; establishing coordination mechanism with the COVID-19 Digital Health Centre for Excellence (DICE) for the provision of technical assistance; supporting the establishment of

[12] The list of EU restrictive measure (sanctions) is reflected in the www.sanctionsmap.eu. Note that the sanctions map is an IT tool for identifying the sanctions regimes. The Official Journal of the European Union is the official source of European Union law and, in case of conflict, its content prevails over that of the Sanctions Map.

national system for detection of counterfeit medicines and other health products and supporting interoperability of pre-existing systems with GTR at multi-country level.

4.4.3. Changes from indirect to direct management mode (and vice versa) due to exceptional circumstances (one alternative second option)

If, due to reasons outside the control of the Commission, the implementation modality foreseen in section 4.4.1 is not possible (procurement), the expected financing could be implemented through a possible indirect management with a pillar assessed organisation or with an EU MS.

If the implementation modality foreseen in section 4.4.2 (Indirect management with an international organisation) is not possible, indirect management will be set-up with another pillar assessed entity.

4.5. Scope of geographical eligibility for procurement and grants

The geographical eligibility in terms of place of establishment for participating in procurement and grant award procedures and in terms of origin of supplies purchased as established in the basic act and set out in the relevant contractual documents shall apply, subject to the following provision. The Commission's authorising officer responsible may extend the geographical eligibility on the basis of urgency or of unavailability of services in the markets of the countries or territories concerned, or in other duly substantiated cases where application of the eligibility rules would make the realisation of this action impossible or exceedingly difficult (Article 28(10) NDICI-Global Europe Regulation).

4.6. Indicative Budget

Indicative Budget components[1]	**EU contribution (amount in EUR)**
Implementation modalities – cf. section 4.4	
Objective 1 External dimension of the EU DCC composed of	
Procurement (direct management) – cf. section 4.4.1	15 000 000
Objective 2 Global Trust Repository composed of	
Indirect management with International Organisation – cf. section 4.4.2)	2 000 000
Evaluation – cf. section 5.2 **Audit** – cf. section 5.3	will be covered by another Decision
Communication and visibility – cf. section 6	0
Contingencies	0
Totals *(Direct Management: total envelope under section 4.4.1: EUR 15 000 000)*	17 000 000

(IM: total envelope under section 4.4.2: EUR 2 000 000)	

4.7. Organisational Set-up and Responsibilities

The African countries and Regional authorities' request to link to the EU DCC external dimension will be managed through the pre-established functional mailbox and committee and will process the requests for equivalence decision. The contracted provider will ensure the deployment of the digital tool in partner countries. To do so, they will be responsible of liaising with relevant EU and AU stakeholders at continental, regional and national level. They will be responsible of setting-up relevant platforms at regional and country level and make the system accessible and user friendly for end-users. They will be responsible of testing the interoperability of the AU-EU tools and monitor and guarantee the safety, the cybersecurity and functionality of the tool.

As part of its support to the Global Trust Repository, the EC expects to take a seat in the GTR Steering Committee, where key governance decisions related to the implementation of the tool will be taken. At this stage, Sweden is part of the GTR, steering committee. The international organisation will be responsible for the deployment of the digital tool at multi-country level ensuring interoperability with the Global Trust Repository. The international organisation will also ensure interoperability is established between the GTR and the pre-existing national systems. The international organisation will be in charge of liaising with relevant stakeholders in country and at regional and global level.

Relevant regional bodies will be consulted for the two actions and relevant accountability frameworks will be discussed/established where relevant.

This action will be coordinated through the pre-established weekly 'Digital Donor Coordination for COVID' working group (Global Fund, Gavi, Bill and Melinda Gates Foundation, GIZ, FCDO, USAID, WHO, UNICEF).

As part of its prerogative of budget implementation and to safeguard the financial interests of the Union, the Commission may participate in the above governance structures set up for governing the implementation of the action.

5. PERFORMANCE MEASUREMENT

5.1. Monitoring and Reporting

The day-to-day technical and financial monitoring of the implementation of this action will be a continuous process, and part of the implementing partner's responsibilities. To this aim, the implementing partner shall establish a permanent internal, technical and financial monitoring system for the action and elaborate regular progress reports (not less than annual) and final reports. Every report shall provide an accurate account of implementation of the action, difficulties encountered, changes introduced, as well as the degree of achievement of its results (Outputs and direct Outcomes) as measured by corresponding indicators, using as reference the logframe matrix.

The Commission may undertake additional project monitoring visits both through its own staff and through independent consultants recruited directly by the Commission for independent monitoring reviews (or recruited by the responsible agent contracted by the Commission for implementing such reviews).

Roles and responsibilities for data collection, analysis and monitoring:

The reporting will be done by the implementing partners for the DCC and the GTR. In the case that the implementing partner cannot undertake the monitoring and reporting, ROM will perform the relevant data collection and reporting, which will be covered in another decision.

Regular meetings with implementing partners will be organised to ensure the milestones are met and stakeholders' needs are taken into account and objectives fulfilled.

For the external dimension of the DCC, monthly updates will be organised with the contractor to ensure milestones are met and troubleshooting is ensured.

For the GTR, monthly meetings through the steering committee will allow to follow the programme development and implementation. In addition, monthly calls with the international organisation will be organised with relevant counterpart in Africa to ensure the smooth deployment of the tool and its uptake.

During the inception phase, baselines and targets will be reassessed and/or developed.

5.2. Evaluation

Having regard to the nature of the action, a final evaluation will be carried out for this action or its components contracted by the Commission.

It will be carried out for accountability and learning purposes at various levels, taking into account in particular the fact that the action will be implemented at the level of the AU, regional and country level.

The Commission shall inform the implementing partner at least 60 days in advance of the dates envisaged for the evaluation activities. The implementing partner shall collaborate efficiently and effectively with the evaluation experts, and inter alia provide them with all necessary information and documentation, as well as access to the project premises and activities.
The evaluation reports shall be shared with the partner countries and other key stakeholders following the best practice of evaluation dissemination[13]. The implementing partner and the Commission shall analyse the conclusions and recommendations of the evaluations and, where appropriate, in agreement with the partner country, jointly decide on the follow-up actions to be taken and any adjustments necessary, including, if indicated, the reorientation of the project.

The financing of the evaluation shall be covered by another measure constituting a Financing Decision

5.3. Audit and Verifications

Without prejudice to the obligations applicable to contracts concluded for the implementation of this action, the Commission may, on the basis of a risk assessment, contract independent audit or verification assignments for one or several contracts or agreements.

6. STRATEGIC COMMUNICATION AND PUBLIC DIPLOMACY

The 2021-2027 programming cycle will adopt a new approach to pooling, programming and deploying strategic communication and public diplomacy resources.

It will remain a contractual obligation for all entities implementing EU-funded external actions to inform the relevant audiences of the Union's support for their work by displaying the EU emblem and a short funding statement as appropriate on all communication materials related to the actions concerned. This obligation will continue to apply equally, regardless of whether the actions concerned are implemented by the Commission, partner countries, service providers, grant beneficiaries or entrusted or delegated entities such as UN agencies, international financial institutions and agencies of EU member states.

[13] See best practice of evaluation dissemination

However, action documents for specific sector programmes are no longer required to include a provision for communication and visibility actions promoting the programmes concerned. These resources will instead be consolidated in Cooperation Facilities established by support measure action documents, allowing Delegations to plan and execute multiannual strategic communication and public diplomacy actions with sufficient critical mass to be effective on a national scale.

APPENDIX 1 REPORTING IN OPSYS

An Intervention[14] (also generally called project/programme) is the operational entity associated to a coherent set of activities and results structured in a logical framework aiming at delivering development change or progress. Interventions are the most effective (hence optimal) entities for the operational follow-up by the Commission of its external development operations. As such, Interventions constitute the base unit for managing operational implementations, assessing performance, monitoring, evaluation, internal and external communication, reporting and aggregation.
Primary Interventions are those contracts or groups of contracts bearing reportable results and respecting the following business rule: 'a given contract can only contribute to one primary intervention and not more than one'. An individual contract that does not produce direct reportable results and cannot be logically grouped with other result reportable contracts is considered a 'support entities'. The addition of all primary interventions and support entities is equivalent to the full development portfolio of the Institution.

Primary Interventions are identified during the design of each action by the responsible service (Delegation or Headquarters operational Unit).
The level of the Primary Intervention is defined in the related Action Document and it is revisable; it can be a(n) (group of) action(s) or a (group of) contract(s).

Tick in the left side column one of the three possible options for the level of definition of the Primary Intervention(s) identified in this action.
In the case of 'Group of actions' level, add references to the present action and other action concerning the same Primary Intervention.
In the case of 'Contract level', add the reference to the corresponding budgetary items in point 4.6, Indicative Budget.

Option 1: Action level		
☐	Single action	Present action: all contracts in the present action
Option 2: Group of actions level		
☐	Group of actions	Actions reference (CRIS#/OPSYS#): <Present action> <Other action>
Option 3: Contract level		
☒	Single Contract 1	External dimension of the EU DCC
☒	Single Contract 2	Roll-out of the Global Trust Repository

[14] ARES (2021)4204912 - For the purpose of consistency between terms in OPSYS, DG INTPA, DG NEAR and FPI have harmonised 5 key terms, including 'action' and 'Intervention' where an 'action' is the content (or part of the content) of a Commission Financing Decision and 'Intervention' is a coherent set of activities and results which constitutes an effective level for the operational follow-up by the EC of its operations on the ground. See more on the concept of intervention.