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ANNEX 1

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

Action Document for Regional dimension and management of the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa

ANNUAL PLAN
This document constitutes the annual work programme in the sense of Article 110(2) of the Financial Regulation, and measures 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**	Regional dimension and management of the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa. [OPSYS/CRIS][1] number: 2021/043-630 Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe).
2. Team Europe Initiative	Yes, it supports the Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa.
3. Zone benefiting from the action	The action shall be carried out in Africa.
4. Programming document	Multiannual indicative programme for Sub-Saharan Africa 2021-2027.
5. Link with relevant MIP(s) objectives/expected results	Priority Area 1: Human Development Specific Objective 1 (Health): Strengthen the African health security architecture, pharmaceutical systems and public health capacity, contributing to stronger, more resilient health systems and improved health outcomes. Result 1.2: Pharmaceutical systems in Africa and the regional manufacturing capacity for vaccines and other medical products and technologies are strengthened to increase quality, safety and equitable access.
PRIORITY AREAS AND SECTOR INFORMATION	
6. Priority Area(s), sectors	Human development, health
7. Sustainable Development Goals (SDGs)	Main SDG: SDG 3 (health) Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all.

[1] Depending on the availability of OPSYS at the time of encoding, a provisional CRIS number may need to be provided.

	Other significant SDGs: SDG 5 (gender equality) SDG 8 (economic growth) SDG 9 (industry and innovation) SDG 16 (good governance) and SDG 17 (partnerships).			
8 a) DAC code(s) [2]	DAC code 1 – 12110, Health policy and administrative management 70% DAC code 2 – 12181, Medical education/training – 5% DAC code 3 – 12250, Infectious disease control – 5% DAC code 4 – 12264, COVID-19 control – 10% DAC code 5 – 32168, Pharmaceutical production – 10%			
8 b) Main Delivery Channel @	Multilateral organisations - 40000 –African Union – 47000 European Union Institutions – 42000 Other – 90000			
9. Targets[3]	☐ Migration ☐ Climate ☒ Social inclusion and Human Development ☐ Gender ☐ Biodiversity ☐ Education ☐ Human Rights, Democracy and Governance[4]			
10. Markers [5] **(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 @	☒	☐	☐
	RIO Convention markers	**Not targeted**	**Significant objective**	**Principal objective**

[2] 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

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

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

[5] 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).

	Biological diversity @	☒	☐	☐
	Combat desertification @	☒	☐	☐
	Climate change mitigation @	☒	☐	☐
	Climate change adaptation @	☒	☐	☐
11. Internal markers[6] and Tags[7]:	**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 o BGUE-B2021-14.020120-C1-INTPA (West Africa): EUR 16 000 000 o BGUE-B2021-14.020121-C1-INTPA (East and Central Africa): EUR 15 600 000 o BGUE-B2021-14.020122-C1-INTPA (Southern Africa/ Indian Ocean): EUR 8 400 000 Total estimated cost: EUR 40 000 000 Total amount of EU budget contribution EUR 40 000 000 This action is an integral part of the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+), to which the EU has pledged EUR 1 billion, announced by President von der Leyen at the Global Health Summit in May 2021. The TEI could benefit, for example, from these contributions: • Deutsche Gesellschaft für Internationale Zusammenarbei (GIZ) was commissioned by the German government/BMZ until August 2023 EUR 8 million to contribute			

[6] 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)

[7] Methodology for additional tagging providing granularity on internal markers is under development.

	to improving framework conditions for local manufacturing in Africa at the regional level; Kreditanstalt für Wiederaufbau (KfW). • France, Belgium and Germany, together with the European Commission, are expected to be the core partners of the mRNA technology transfer hub launched by WHO France is supporting the hub with EUR 20 million. This action will also complement enlarged Team Europe technical and financial support by the EU, EU Member States and European financing institutions in countries, for example: • In Senegal: Agence française de développement (AFD), KfW Development Bank, European Investment Bank, Belgium and the European Commission work together as Team Europe, and coordinate with the International Finance Corporation (IFC) / World Bank Group, U.S. International Development Finance Corporation, U.S. Agency for International Development (USAID), GIZ, Physikalisch-Technische Bundesanstalt (PTB) • In Rwanda: Enabel, PTB. • In South Africa: GIZ, KfW, Deutsche Investitions (DEG), PTB. • In Ghana: GIZ, PTB.
MANAGEMENT AND IMPLEMENTATION	
13. Type of financing[8]	**Direct management** through procurement and direct grant. **Indirect management** with the entities to be selected in accordance with the criteria set out in section 4.4.

1.2. Summary of the Action

The multiannual indicative programme (MIP) for Sub-Saharan Africa 2021-2027 includes human development as its first priority area. Within this priority, the specific objective 1 is strengthening "the African health security architecture, pharmaceutical systems and public health capacity, contributing to stronger health systems and improved health outcomes". More specifically, result 1.2 refers to reinforcing "the African pharmaceutical systems and the regional manufacturing capacity for vaccines and other medical products and technologies" to increase "quality, safe and equitable access". This result will contribute to lay the foundation for an innovative pharmaceutical and health care industrial sector in Africa integrated into the global health architecture. It will underpin the health and well-being of future generations. The right to health sets the stage for the right to an adequate standard of living, because good health is key to securing and maintaining a job. Supporting local manufacturing and access to all essential health products and technologies represents an opportunity to target several development objectives and geo-political priorities shared by both the EU and the African Union (AU), stimulate growth and decent jobs, facilitate trade, diversify global value chains, engage with the private sector, mobilizing its technical expertise and financial power, and reinforce our scientific and diplomatic ties with partner countries while advancing universal health coverage (UHC) and human development.

This regional action is an integral part of the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+), which also encompasses interventions at country level (for fiscal year 2021 concrete actions are foreseen in Senegal, Rwanda and South Africa, and dialogue is ongoing on possible actions in Ghana, Nigeria, Ethiopia, Kenya, Botswana or Guinea). National actions complement the regional actions by focusing on production and manufacturing plants, removal of barriers and strengthening national pharmaceutical sector. This action will also benefit from the EU influence in main global health initiatives: Gavi, COVAX (COVID-19 Vaccines Global Access) –and its Manufacturing Task Force– and The Global Fund to Fight AIDS, Tuberculosis and Malaria. This action represents an initial step to advance this agenda and allows for better coordination, enhanced technical assistance and a reinforced stewardship of the TEI.

[8] Art. 27 NDICI

This action document covers a first allocation of EUR 40 million, which will be followed by other actions. It aims to establish the the European Union as a reliable partner for Africa, build on bilateral initiatives of EU Member States, and enhance the reach and coherence of the interventions by other actors such as the European Investment Bank (EIB) and the European Medicines Agency (EMA).

These new partnerships around the TEI MAV+ will link and unfold synergies with other AU-EU partnerships and initiatives established in relevant domains, such as health research and innovation, public health and digital transformation, e.g. the European and Developing Countries Clinical Trials Partnership (EDCTP), the AU-EU High Level Policy Dialogue (HLPD) on Science, Technology and Innovation, the Policy and Regulation Initiative for Digital Africa (PRIDA) or partnerships paving the way "Towards a comprehensive strategy with Africa" (trade, industry, technological innovation, AEIP project, inequalities, other health).

It recognises the political imperative of supporting progress on vaccine manufacturing and access to COVID-19 vaccines, and it seeks to differentiate the European Union from other partners in two ways, first, through establishing its credentials in support of the broader agenda on access to medicines, access to innovation and strengthening systems and, secondly, through helping African actors and solutions deliver for Africa's challenges. It lays the basis on which the EU's strategy in support of local pharmaceutical production in Africa can be refined and implemented.

This action will provide direct and indirect support to African initiatives and mechanisms, notably the AU-led Partnerships for African Vaccine Manufacturing (PAVM) launched in April 2021, and is being programmed in anticipation of the AU-EU Summit taking place on 17-18 February and the associated AU-EU Business Forum (EABF) that will provide an opportunity for detailed deliberations with the private sector.

The intervention logic of this regional action will focus on four objectives (further detailed in section 3):

1. Advance regulatory convergence, harmonisation and use of reliance mechanisms between regulatory authorities from both continents.
2. Initiate technology transfer and innovation for local production.
3. Improved platforms for demand consolidation and strategic purchasing.
4. Enhanced coordination, leadership and programme governance.

The present action will be complemented by a separate regional intervention aiming at enhancing the safe delivery of pharmaceutical and biotech goods, including across borders through improved digital supply chain management. A global trust repository (GTR) initially for COVID-19 vaccines is under development as a tool to ensure supply chain integrity and combat counterfeit and falsified vaccines and medicines.

Furthermore, under EU and AU leadership, and in partnership with the private sector, European, African and International financing institutions, private banks and investment funds, jointly or individually, the EU will nurture financing opportunities and vehicles to fund the establishment or expansion of companies and entrepreneurs in the biotech, pharma or health care technology sectors in Africa. Considering the overarching goal of strengthening health systems and pursuing universal health coverage, the EFSD+ investment windows could incentivise and de-risk investments and promote public-private partnerships in the pharmaceutical and biotechnology sectors.

In alignment with the Commission's health policies in partner countries, the overarching SDG target being pursued is SDG 3.8: "achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all." Other connected SDGs are SDG 8 (economic growth), SDG 9 (industry and innovation), SDG 10 (reduce inequality between and among countries), SDG 16 (good governance) and SDG 17 (partnerships).

Consequently, the concerned DAC codes are related to health (12110, health policy and administrative management; 12181, medical education/training; 12250, Infectious disease control; COVID-19 control) and industry (32168, pharmaceutical production).

2. RATIONALE

2.1. Context

Development aid to pharmaceutical systems and developing manufacturing capacity for vaccines and other medical products represents an opportunity to open a new chapter in Africa's industrial development, stimulate growth and create novel jobs with decent work standards and accessibility by workers with disabilities, boost trade, diversify global value chains, engage with the private sector, and reinforce EU's scientific and diplomatic ties with partner countries.

From the perspective of internal dynamics and policy coherence, the broader initiative and this action in particular are a presidential priority aligned with and complementary to Horizon Europe, the EU research and innovation framework programme and its partnerships (e.g. Global Health European and Developing Countries Clinical Trials Partnership 3 –EDCTP3-Joint Undertaking); the new EU4Health initiative; and the Pharmaceutical Strategy for Europe adopted in November 2020.

Both the current health and economic crises have highlighted a number of critical issues that need to be addressed to improve preparedness, health security and health outcomes globally and particularly in Africa. As of August 2021, Africa is in the midst of a third wave of COVID-19 infections and has been unable to achieve significant COVID-19 vaccination coverage, to a great extent due to the continent´s reliance on highly constrained international manufacturing capacity at a time of high global demand. There is an imperative to increase vaccination rates way beyond the current 5%, requiring that more doses become available for the continent in the near future. It is vital that global vaccine manufacturing capacity is expanded and diversified. This opens opportunities for Africa to develop its pharmaceutical sector and to ensure that, moving forward, the continent has secure sources of supply for its priority vaccines, also in the event of future pandemics. Pharmaceutical companies have responsibilities regarding the realization of the right to health, in particular relation to access to medicines and vaccines. AU Member States and regional organizations should work to protect the health of their citizens, while pursuing public health objectives, and provide access to medicines for all, in particular for groups living in vulnerable situations (people living with disabilities, women, elderlies, children and those living in fragile contexts). Access to medicines and vaccines is an important building block of health systems strengthening. .

Amongst the international community there is currently a strong focus on expanding vaccine manufacturing capacity for COVID-19 vaccines in Africa. Development Financing Institutions (DFIs), bilateral and multilateral donors are supporting the few existing vaccine manufacturers such as Institut Pasteur in Senegal and Biovac in South Africa to build manufacturing capacity that could be utilised for production of COVID-19 vaccines. International manufacturers have also taken bilateral initiatives to expand COVID-19 vaccine manufacturing in Africa, such as the Johnson&Johnson (J&J) agreement with Aspen and the Pfizer-BioNTech deal with Biovac, both of which are for downstream manufacturing activities and are expected to lead to a combined capacity of 500 million doses per annum by end of 2022. This expansion is essential to respond to current needs of covid-19 vaccines, and should be considered as a first step into ensuring future local production of other routine vaccines. Women are essential in the health workforce but are not adequately represented in vaccine manufactures or decision making forums.

The objectives and activities of this action will have strong development, commercial and political impact. The EU is not only Africa's neighbour, but also its primary commercial partner. Likewise, the initiative responds to the call of African leaders. In April 2021, the African Union, under the leadership of the Africa Centre for Disease Control and Prevention (CDC), launched the Partnerships for African Vaccine Manufacturing (PAVM) laying the foundations for the development of a biotech industry integrated into global supply chains. The AU has firmly put forward a vision of strengthening vaccine manufacturing in Africa so that 60% (versus current 1%) of vaccine needs can be met from Africa sources by 2040. To achieve this end, it is seeking support from international donors, technical agencies and others. The Africa CDC together with AUDA-NEPAD (Africa Union Development Agency - New Partnership for Africa's Development) are two of the main regional actors pursuing this agenda together with private operators active in African market(s). The Commission is preparing a joint roadmap and deliverables for the AU-EU Summit in 2022 and a number of EU Member States are already working hand in hand with these institutions.

The COVAX Manufacturing Task Force is also looking at vaccine manufacturing capacity constraints in low and middle income countries (LMICs) and with an initial focus on COVID-19 vaccines. It has established a technology transfer hub model, and in conjunction with partners (e.g. Medicines Patent Pool –MPP-, Afrigen, Biovac, South

African Medical Research Council –SAMRC-, Africa CDC), World Health Organisation (WHO) has announced in June 2021 that the first hub focussing on mRNA vaccines will be established in Cape Town, South Africa.

As well as the area of vaccines, the pandemic has also highlighted the importance of local production of other health products such as therapeutics, diagnostics or personal protective equipment (PPE). It is estimated that 2 billion people do not have access to safe and effective essential medicines, many of whom are living in Africa. Increased global demand and the transport delays that were particularly debilitating for global trade during the earlier phases of the pandemic led to supply disruptions for essential medicines, compounding an already tragic situation. Whilst Africa has in the order of 600 manufacturers of small molecule therapeutics, it still imports the vast majority of finished products (over 90%) and is reliant on other regions for virtually all inputs (e.g. active pharmaceutical ingredients – APIs, excipients, bottling, packaging) for local production. To a greater or lesser extent nearly all countries on the continent are subject to significant penetration of substandard and falsified (SF) pharmaceuticals. Strengthening the pharmaceutical manufacturing industry, its supply chain logistics and monitoring on the continent could help address the SF challenge, increase availability of essential medicines, and through regionalising value chains increase heath security in the event of future pandemics or other crises. On the other side, combating SF through other means, e.g. facilitating the establishing a Global Trust Repository (GTR) and of a true traceability system in Africa –through a complementary action-, will increase the trust of private companies, investors and consumers, thus acting in synergy with the Initiative on manufacturing to creating an enabling environment for production and use of health products.

The pandemic has reignited the fierce debate on intellectual property (IP), patents and access to medicines, with an application for a waiver of certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (known as TRIPS) being made to the TRIPS Council at the World Trade Organization (WTO) by India and South Africa. Whilst it is widely acknowledged that the patent system has been instrumental in enabling development of COVID-19 vaccines so rapidly, that is of little comfort to many countries in the Global South who are unable to source these innovative products for their citizens. Existing mechanisms and flexibilities in the TRIPS agreement provide already a good basis for accelerating access to innovation to meet public health priorities, but realising these opportunities requires a concerted effort to develop productive capacities, establish regional value chains for health products, and incentivise technology transfer. Intellectual property on vaccines goes far beyond patents on the final compound: manufacture of the drug product usually draws on a range of patents and licensing agreements covering excipients, adjuvants, genetic expression systems, etc. Besides, securing patent rights does not in itself enable successful production of a comparable vaccine. This requires access to cell banks, lipids and plasmids, specifications and analytical methods, as well as detailed process knowledge These are not only proprietary, they are project specific and they form a highly complex body of know-how. The specialised literature has revealed the existence of numerous barriers to access ranging from poor regulatory frameworks to lack of skilled personnel or deficient public and private financing and pricing policies, to name a few. The action document is conceived to tackle the root causes of those barriers and generate the right incentives.

2.2. Problem Analysis

The African continent is today home to 1.3 billion people. By 2050, the population is expected to have reached at least 2 billion people. It accounts currently for 25% of the global disease burden but much of its population has limited access to the safe and effective medical products they need. The risk of poor-quality medicines remains a major threat to patients and economies. The ongoing COVID-19 pandemic has highlighted the vulnerabilities of existing global supply chains for all vaccines, medicines, health technologies, and products for sexual and reproductive health, and the fact that much of Africa relies on international imports. Both local manufacturing –targeted by this initiative- and the need for broadening and diversifying global value chains opens opportunities for Africa's industrial development and contributes to improve access to the essential health products. Gender-related barriers must be addressed in the planning and rollout of vaccine distribution to reach everyone. Women face limited mobility to reach health facilities or vaccination sites, restricted decision-making power in their health seeking as well as limited access to and control over resources needed for advancing their health, including information about vaccines and vaccine safety. Also people living with disabilities and in fragile settings (like conflict areas or internally displaced) face increased difficulties in having access to safe vaccines and medicines, including the COVID-19 vaccine. Africa currently imports 99% of its vaccines and more than 90% of all medicines and health technologies. Therefore, strengthening local manufacturing of and thereby improving access to quality vaccines, medicines and medical technologies is a priority for our African partners. It represents an opportunity not only to enhance health outcomes, but also for the

EU to partner strongly with Africa and support the continent to leapfrog into sustainable innovation, and support governments and regional organisations to put in place policies and enforcement measures to organize the sector (decent work conditions in local manufacturing, right to health for all even for groups living in vulnerable situations, business ethics). The local manufacturing also provides an opportunity to promote gender equality and inclusion of persons with disabilities to employment.

To help address the many barriers, the broader Team Europe Initiative (TEI) will leverage resources from the European Commission, European financing institutions and EU Member States. An integrated, multi-layered and comprehensive support package will tackle barriers to manufacturing and access to health products and technologies in Africa from different angles, and will place the continent's own actors and institutions at its heart. It will encompass support under 3 dimensions: 1) **supply side**, 2) **demand side** and the 3) **enabling environment** health and pharmaceutical systems. Based on the overall TEI, which follows a 360-degree approach, specific actions will be envisaged around:

1) The **supply side**
   - Industrial development
   - Financing manufacturing (establishing financing vehicles and instruments de-risking private investments).
   - Technology transfer.
   - Quality assurance system throughout the supply process to address the constraints that negatively impact the availability, affordability and acceptability of essential medicines and vaccines, and a modern mix of quality-assured SRH-commodities.
2) The **demand side**
   - Market shaping, demand defragmentation and consolidation, business plans, and addressing market failures for medicines and health products.
   - Health promotion and risk communication for the final users or communities.
   - Building trust and confidence of local communities in locally manufactured health products.
3) The **enabling environment and pharmaceutical systems**
   - Improving regulation and governance of health products, including coherent national policies that provide the right incentives and ensuring that essential medicine lists include key commodities, including SRH commodities.
   - Promoting human capital development.
   - Supply chain management and integrity.
   - Trade facilitation (reduce tariff and non-tariff trade barriers for the movement of raw materials and finished products across the continent).Research and innovation capacity and regulatory progress.

This agenda involves numerous stakeholders at multiple levels across multiple different domains. Achieving the health objectives requires coordinated action on related issues such as trade, industrial development and finance.

At a continental level, the main organs of the African Union (AU) that will be critical for MAV+ are: the AU Commission (AUC), the Africa Centres for Disease Control and Prevention (Africa CDC) and the African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD). The AUC provides the crucial political link to the continent’s leadership, while the Africa CDC has a vital role in driving the public health and pandemic preparedness dimensions and, very specifically in this context, in providing the secretariat for the PAVM. AUDA-NEPAD has a broad developmental mandate, including a track record in supporting regulatory harmonisation. The AU can also help expand the Commission’s engagement with Regional Economic Communities (RECs) and ensure that AU Member States are actively engaged to ensure that different perspectives and ambitions are reflected as a basis for inclusive and sustainable progress according with the UN Guiding principles on Business and Human Rights. As duty bearers, regional organizations and AU Member States have to develop a general framework of the sector as well as the protection of public health risks (right to privacy, personal data…).

Likewise, the international community has a pivotal role to play. WHO is a key enabler given its role as global normative health agency with a regional and national mandate and structure in Africa. This action will strengthen WHO’s leading role in the COVAX Manufacturing Task Force and as co-chair of the AMRH secretariat. Other international public health entities with critical mandates include Gavi, UNICEF (United Nations Children's Fund), and the Global Fund which have substantial influence. The World Bank and its private arm –the International

Financial Corporation (IFC)–, the World Trade Organization (WTO), the United Nations Conference on Trade and Development (UNCTAD), or the United Nations Industrial Development Organization (UNIDO) are also pursuing this agenda. Bilateral donors like the United States have demonstrated and increasing appetite for health industry development, as have a number of private foundations, particularly the Gates Foundation.

Key stakeholders include the European Medicines Agency (EMA), which is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. Its mandate includes international activities and, as it is globally the only regional medicines regulatory agency it is a model for the upcoming African Medicine Agency (AMA). In this regard, EU financing support under this Action plan for manufacturing and access to vaccines, medicines and health technologies in Africa should take in consideration EMA's approval of effective and safe products. Support through the EMA will be foreseen in 2022. EU Member States and financing institutions such as the European Investment Bank (EIB), Proparco, Bio or KfW are embarking on operations in this domain.

The private sector, in its many different guises needs to be engaged to deliver the requisite progress. African pharma companies, med-tech manufacturers, private sector investors, international research & development based manufacturers, generics and med tech companies can all play a critical role and through its broad range of coordinated engagement, MAV+ will leverage the role of private sector to deliver sustainable impact. Growth of the sector should guarantee access to decent jobs opportunities according with the ILO fundamental Conventions banning forced labour, offering minimum labour age, ending discrimination, supporting freedom of organization, supporting equal remuneration, etc.

Patients, civil society and youth organisations, and product development partnerships (PDPs) are activists in the access to medicines context. They provide an important voice that needs to be heard and capabilities that can be leveraged particularly in discussing future priority diseases and in the promotion of the right to health.

3. DESCRIPTION OF THE ACTION

3.1 Objectives and Expected Outputs

The **Overall Objective (Impact)** of this action is to facilitate **equitable access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all African**s. This objective pursues SDG 3.8 and promotes ultimately universal health coverage (UHC). Its attainment requires reinforcing African pharmaceutical systems and the regional manufacturing capacity.

The **Specific Objectives (Outcomes)** of this action, as mentioned in section 1.2, are the following four:

1. Advance regulatory convergence, harmonisation and use of reliance mechanisms between regulatory authorities.
2. Initiate technology transfer and innovation for local production.
3. Improve governance for demand consolidation and strategic purchasing.
4. Enhance coordination, leadership and programme governance (implementation unit) to strengthen African pharmaceutical systems.

The four objectives are of high strategic importance to underpin the continental dimension of the TEI on manufacturing and access to vaccines, medicines and health technologies (MAV+), which aims to provide comprehensive support (a "360° package") to tackle barriers to manufacturing and access to health products and technologies in Africa. It is conceptualised around 3 dimensions: 1) supply side (manufacturing), 2) demand side and 3) enabling environment. Therefore, the first three objectives are directly linked to (and at the core of) these dimensions and will cover activities that the private sector, financing institutions, governments and civil society alone cannot accomplish; activities that need to be incentivized through grants and strong multi-stakeholder policy dialogue. The fourth dimension is vital to mobilise and coordinate resources and make the most of the broader TEI.

1. The expected **Output under Specific Objective (Outcome) 1** (advance regulatory convergence, harmonisation and use of reliance mechanisms between regulatory authorities from both continents to address regulatory bottlenecks) are:

- The African Medicines Agency (AMA) is established and through it regulatory convergence, harmonisation and use of reliance mechanisms are promoted across National Regulatory Agencies (NRAs) and Regional Economic Communities (RECs).

2. The expected **Output under Specific Objective (Outcome) 2** (initiate technology transfer and innovation for local production, including skills development) is:

- An mRNA technology transfer hub (or any similar structure promoting health technology transfer ecosystems) is established and adequately coordinates and operationalises technology transfer across Africa, supporting gender-sensitive skills development programmes.

3. The **Outputs** to be delivered by this action contributing to the **Specific Objective (Outcome) 3** (improved platforms for demand consolidation and strategic purchasing) are:

3.1. Platforms for African partners to engage in strategic purchasing and demand consolidation for healthcare products (e.g. the PAVM is setting up a market design and demand intelligence pillar) are developed.
3.2. Demand and pricing dynamics of critical products across the value chain are better known, incentivising European partners to responsibly invest in Africa (e.g. through the analytical work and market shaping activities being conducted by the WHO-backed mRNA technology transfer hub, and in line with the UN Guiding Principles on Business and Human Rights).

4. The **Outputs to be delivered by this action contributing to the Specific Objective (Outcome) 4** (enhanced coordination, leadership and programme governance) are:

4.1. Enhanced support structure for all work streams under the TEI to help underpin the global leadership role of the EU, which will ensure that the EU delivers on its objectives.
4.2. The PAVM Secretariat and the work streams of its strategy are fully operational and in synergy with the TEI.

3.2 Indicative Activities

Activities related to Output 1

1.1. Provide technical support to AUDA-NEPADs AMRH through its RECs MRH programmes and AMRHs Technical Committees (Continental Technical Working Groups), specifically:

a) African Vaccines Regulators Forum (AVAREF) – for regulation of clinical trials;
b) African Medical Devices Forum (AMDF) – for regulation of medical devices (including in-vitro diagnostics);
c) African Medicines Quality Forum (AMQF)– for market surveillance of medicines;
d) African Blood Regulators Forum (ABRF) – for regulation of blood and blood products;
e) Africa Pharmacovigilance (PV) Advisory Group (APAG) –to coordinate many fragmented PV initiatives on the continent and the development of a coherent framework for PV in Africa, including establishment of a regional network of sentinel sites for the active safety surveillance of new priority medicines and vaccines.

1.2. Accelerate the formal establishment of AMA by providing technical assistance based on WHO and EU policies, standards and guidelines for regulation and registration of key medical products (medicines, vaccines, SRH products);
1.3. Facilitate knowledge and assets transfer from the secretariat of AMRH at AUDA-NEPAD to AMA to support a smooth transition.

1.4. Support setting up of regulatory infrastructure for AMA, including e.g. regulatory information management systems (RIMS) for information sharing across NRAs and RECs across the continent.
1.5. Support regulatory functions with special regional importance (e.g. inspections or strengthen regional post marketing surveillance programmes).
1.6. Develop human resource capacity for regulatory systems strengthening in Africa, including e.g. developing a human resource and capacity development plan (gender-sensitive and inclusive of persons with disabilities), facilitate the establishment of the AMA Secretariat, guarantee standards on decent work, facilitate institutional and organisation gender analyses and develop gender policies, etc.
1.7. Support the establishment of sustainable financing policy for AMA, together with other partners.
1.8. Support for the implementation of institutional developments plans (IDPs) of NRAs following benchmarking using the WHO GBT[9] in priority countries and support to regulatory functions relevant for regional collaboration and work-sharing.

Activities related to Output 2:

2.1. Support technology selection, negotiate, secure and manage licences. This will follow a balanced approach inclusive of mRNA technology but not limited to it.
2.2. Engage with originators of existing SRA and EMA-approved vaccines pursuing bilateral technology transfer agreements, and define with industry the type of deals that would be acceptable for technology transfer. Other products could be considered (e.g. biosimilars or some generics whose formulation is complex or where bio-equivalence is difficult to demonstrate).
2.3. Cost options, develop business plans and market shaping strategy.
2.4. Define governance.
2.5. Identify and select appropriate territories, number of spokes and technology recipients.
2.6. Develop and implement appropriate tools and technical operations, including e.g. the design of incentives to the industry to promote technology transfer, or a gender-sensitive and inclusive human resource development strategy to train and retain the required manpower in cooperation with universities and vocational training institutions.
2.7. Practical training for analytical, operating and technical staff.
2.8. Together with other activities under output 1, advance good manufacturing practices (GMPs) and ensure regulatory approval, which requires demonstrating the comparability of the product.
2.9. Support adequate intellectual property management prioritising voluntary deals.
2.10. Support the establishment of local production by removing tariff and non-tariff barriers affecting inputs necessary for the production of the pharmaceutical products for relevant research and technology transfer.

Activities related to Output 3.1: (primarily through the PAVM)

3.1.1 Encourage more African companies to prequalify priority products, thus opening up significant donor funded markets for leading local manufacturers (in connection to action 1.2.3).

3.1.2. Technical assistance to the market design and demand intelligence working group under the PAVM (gender experts and representative of CSOs will be involved).
3.1.3. Promote health technology assessment (HTA) tools.
3.1.4. Facilitate the engagement between African leaders and the Global Fund, UNFPA, UNICEF and other pooled funds to explore how their procurement activities can have a greater pull effect on investment in international standard manufacturing capacity in Africa, in line with the UN Guiding Principles on Business and Human Rights.
3.1.5. Engage with the AU, ACDC, AUDA-NEPAD and the RECs to explore mechanisms by which greater market transparency can be achieved, leveraging the work of partners such as the market data initiative by the Medicines for Malaria Venture.
3.1.6. Promotion of acquisition of quality-assured products.
3.1.7. Promotion of reduction of tariff and non-tariff barriers across the African continent to the acquisition of pharmaceutical raw materials and trade of finished goods produced in Africa.

Activities related to Output 3.2: (primarily through the COVAX Manufacturing Task Force)

[9] https://www.who.int/tools/global-benchmarking-tools

3.2.1. Active EU participation in the dialogue promoted by the ACT-A and COVAX Manufacturing Task Force, notably under the mRNA technology transfer hub.

Activities related to Output 4.1:

4.1.1. Multi-country support building on lessons learned and experiences, particularly to EU Delegations.
4.1.2. Support the coordination and knowledge exchange across line DGs (technically and logistically): with NEAR, ECHO, EEAS,RTD, JRC, GROW, TRADE, SANTE.
4.1.3. Facilitation the planning for joint programming and other forms of collaboration with EU Member States.
4.1.4. Better engagement with the private sector.
4.1.5. Technical inputs for political dialogue in the context of international initiatives (e.g. ACT-A and COVAX Manufacturing Task Force) and the PAVM.
4.1.5. Inputs for strategic communication strategies (including information and sensitisation of women, groups at risk and persons with disabilities about access to affordable, accessible to medicines and vaccines in a diversity of accessible formats with use of accessible technologies).
4.1.6. Support to monitor progress of the initiative.

Activities related to Output 4.2:

4.2.1. Support the staffing of the PAVM Secretariat and strengthen its organisational capacity to deliver across all work streams of its strategy.

On a final note, EU Member States are starting to contribute to this agenda with several activities and the European Commission will ensure alignment of efforts under the TEI.

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.

3.3 Mainstreaming

Environmental Protection & Climate Change
N/A

Given the nature of the Action, there is no need to undertake an SEA screening, EIA (Environmental Impact Assessment) screening or a CRA (Climate Risk Assessment) screening.

Nevertheless, on March 2019, the Commission adopted a strategic approach to pharmaceuticals in the environment as required by Article 8c of Directive 2008/105/EC as amended by Directive 2013/39/EU. The approach covers all phases of the lifecycle of pharmaceuticals, from design and production through use to disposal. This will guide the exchanges with partners on these matters.

Gender equality and empowerment of women and girls
As per OECD Gender DAC codes identified in section 1.1, this action is labelled as G1.

At all stages gender-responsive human rights-based approach principles participation, non-discrimination/equality, accountability and transparency applying to all rights will guide the planning and implementation of the Action.

Gender is an important factor influencing caregiving as well as demand, access and use of health services including immunisation services for woman and their children particular in times of scarcity and in fragile settings, with weak health systems. Reducing scarcity of crucial health products like currently the COVID-19 vaccine and other routine vaccines as often occurs in Africa, has thus a direct impacts on women's and children's lives. Likewise, women are a significant majority among first line healthcare workers that are involved in the fight against COVID-19 pandemic, and their role in biochemistry, immunology, genetics, pharmacy, biochemical engineering and engineering generally

is growing. As such, they will be part of the leaders promoting the manufacturing and access to health products agenda. In settings where cultural barriers prevent women from accessing jobs in these sectors, initiatives to increase the number of female workers, technicians, service providers and leaders can be supported. The action contributes to the Gender Action Plan III (GAP III, 2021-2025), more specifically area "promoting economic and social rights and empowering girls and women".

Many guidelines and documents on how to integrate the gender dimension and the rights-based approach into the COVID-19 responses are developed by international organizations (UN Women, UNDP, WHO…) and can be helpful during implementation of the action.

Human Rights

Access to safe and effective medicines and vaccines is a human right. Human rights principles will be central in the implementation of the action. Vulnerable and fragile groups, often excluded from access to health care, are also going to profit from the outcomes of this action, as one of the overarching objectives is equitable access to health products and technologies. Analyses and assessments will be conducted to incorporate specific work on Business and Human Rights and mainstream the rights-based approach and responsible business conduct. New policies and action plans will be transparent and communication campaigns will support transparency and participation for all. Special supports from gender and human rights experts will be included during the implementation phase for analyses and studies. Particular attention will be paid to ensuring full respect for human rights and equal treatment of all.

Disability

Persons with disabilities and pre-existing conditions (particularly in rural areas and the elderly) are considered as particular vulnerable for COVID-19 and other infectious diseases. Additionally, they are at greater risk due to inaccessible information about vaccination and access to vaccination sites or other supply chains limitations. The European Commission will work with national and international partners to ensure that nobody is left behind in future vaccination programs. As per OECD Disability DAC codes identified in section 1.1, this action as D1. The action will pay particular attention to facilitate participation of persons with disabilities in the skills building, training activities, and consultations and in created employment. Accessibility to information and buildings (universal design) will be promoted and reasonable accommodation will be provided for participants and staff with individual needs.

Democracy

The action does not tackle democratic processes. However, it will contribute to build better institutions (e.g. African Medicines Agency –AMA– and indirectly to integrate patients groups in those institutions. By enhancing regulatory frameworks the action supports good governance and the environment that facilitates access to quality, affordable, safe health products. Good governance will also involve dialogue with patients groups. Patients, civil society and youth organisations, products development partnerships, and health and pharmaceutical industries, welcomed the (AMA Treaty and actively participate in existing international dialogues and platforms. In February 2021, these organisations have called all AU Heads of State to ratify the AMA treaty. WHO and the EU will play an instrumental role, through component 1 of this proposal, to make the AMA a reality. In April 2021, during the preparatory phase, the Commission presented the main features of the initiative to CSOs who welcomed it.

Conflict sensitivity, peace and resilience

The action will promote health systems resilience, pandemic preparedness and global health security. An ongoing complementary action (Special measure in favour of contributing to the availability and equitable access to COVID-19 vaccines in low and lower-middle income countries through the COVAX Facility) takes into account the conflict sensitivity and reconciliation efforts in partner regions. Populations in territories with unresolved and/or ongoing conflicts, asylum seekers and refugees are disproportionately affected by the current health crisis due to restrictions in movements, limited humanitarian aid and limited access to and lack of proper health care services. Secured by COVAX AMC donor funding, the COVAX Facility foresees the distribution of at least 100 million doses through its Humanitarian Buffer to those regions and territories most in need.

Disaster Risk Reduction

COVID-19 pandemic has created incredible damage to societies and economies globally. Preventing the further spread of this infection and the development of new pathogen variants is a prerequisite for returning to normality. Vaccination is the only proven and efficacious prevention method, which requires great quantities of vaccines over a longer period of time equally distributed throughout the world. This measure will contribute to this global goal directly

by scaling up local production of COVID-19 vaccines (and other products). In addition, enhancing access to safe, effective, quality and affordable essential vaccines, medicines and health technologies will necessarily improve health outcomes, can enhance response capacity and diminish the risk posed by the many epidemics that recurrently affect the African continent.

Other considerations if relevant

Human health is a fundamental value and an investment in economic growth and social cohesion. Healthy individuals are more likely to be employed and less likely to be socially excluded. A healthy workforce is more productive, and healthcare services and health industries (pharmaceuticals, medical devices, and health research) are an important knowledge-intensive economic sector that enables people to maintain and improve their health and creates a steady demand for workers.

3.4 Risks and Lessons Learnt

Category	**Risks**	**Likelihood (High/ Medium/ Low)**	**Impact (High/ Medium/ Low)**	**Mitigating measures**
External environment	Risk 1: - Numerous initiatives focusing on vaccine production and broadly in the pharmaceutical sector can lead to overlaps, duplication of efforts and inefficiencies in the support provided.	**Medium**	**Medium**	Objective 4, which will promote strong coordination of European initiatives through a Team Europe approach with the AUs PAVM, starting with information sharing and coordination with the other Commission services through an existing ad hoc project team; coordination with key donors and partners (e.g. US, World Bank, UK, Gates Foundation), which is already happening through platforms such as the COVAX Vaccine Manufacturing Working Group.
External environment	Risk 2: - Overlapping institutional mandates (between AU and other regional organisations – RECs-, Africa CDC, AUDA-NEPAD and WHO etc.) can lead to undesired fragmentation and inefficiencies.	**Medium**	**Medium**	EU to leverage the strategic dialogue organised alongside the capacity building work to mitigate the issue of overlapping mandates. Alignment around the main continental strategies (PAVM, AMRH) will prevent a narrow sub-regional or project focus.
	Risk 3: - Risk aversion of private sector and financial institutions limiting investments in health and the pharmaceutical sector.	**Medium**	**High**	Promotion of DFI consortia and the incorporation of blending and guarantees to reduce financial risks on lending, and the use of technical assistance tools.
Planning, processes and systems	Risk 4: High level of complexity given for example the	**High**	**High**	The overarching strategy for the TEI will focus on the key levers that can be used to affect change, will empower African

	array of different issues, stakeholders and partners. This could hamper strategy implementation and the realisation of impact.			ownership and institutional development, will identify our comparative advantage, and will establish a coordination and governance initiative to monitor internal and external developments and recommend course corrections as the need arises. The specifics of follow up actions will be informed by the collective learnings of the TEI.
People and the organization	Reduction in the current level of political interest in this agenda could hamper coordination across TEI in the longer term.	**High**	**High**	Momentum and enthusiasm amongst partners in the Team Europe Initiative will be built and harnessed through communications and awareness raising. The strategy will be developed on the basis of our full range of capabilities, whilst ensuring that different components can deliver impact in their own right.
Communication and information	-Communication methods and channels; - Quality and timeliness of information. Risk of low visibility inherent in supporting a multilateral/UN organisation levels.	**Medium**	**Low**	It will be mitigated by actively engaging with implementing partners to ensure the EU has a primary role in policy dialogue at HQ and EUD/country, notably on the promotion of EU interest when it comes to technology transfer and innovation for local production.
Planning, processes and systems	The high level of complexity with many stakeholders (governments/institutions, services providers, local manufacturing…) developing the sector introduce risks of corruption and/or conflict of interest	**Medium/high**	**High**	Regional organisations and governments should be developing legal framework promoting transparencies, responsible sale, affordable and accessible medicines but also protecting the sector against counterfeit medicines and vaccines. Legal framework has to be developed further according with experiences from WHO, UNICEF, UNFPA and EU in line with the UN Guiding Principles on Business and Human Rights

Lessons Learnt:

General EC experience

The Commission has a track record of supporting pharmaceutical systems in Africa. The Commission provided EUR 25 million to finance the EU/ACP/WHO Partnership on Pharmaceutical Policies over the period 2004-2010, with a second program in the period 2011-2017 of EUR 10 million contributing to the EU/ACP/WHO Renewed Partnership to strengthen Pharmaceutical Systems in 15 Sub-Saharan countries. The results of the evaluation of the latter have been taken into account to define this new action, being more targeted than previous ones. The new action being proposed now also looks at the specific value of the EU as a regional entity itself and in comparison to other donors active in this space (e.g. USAID), and intends to complement the solutions and resources offered by international/development financing institutions.

Currently, the EU-WHO Health Systems Strengthening for Universal Health Coverage Partnership Programme incorporates an access to medicines, vaccines and health products component focusing on regulatory functions, procurement capacity, review and assessment in particular examining quality, availability, pricing and expenditure and rational prescribing. Likewise, the Commission has provided financial support to the WHO *Global Strategy and*

Plan of Action on Public Health, Innovation and Intellectual Property. Current support focuses on encouraging innovation and improving access to essential medicines and health technologies, supporting the WHO Global Observatory on Health R&D innovation and improving delivery and access to quality medical products. The next steps will build on these experiences and the knowledge and evidence generated by them, while adding new dimensions.

This action will also seek synergies with ongoing country level actions (starting with Senegal, Rwanda and South Africa), ongoing regional actions (SIPS), and with EU-funded global health initiatives such as COVAX, Gavi and The Global Fund. In particular, the Support to Industrialization and the Productive Sector (SIPS) initiative was launched in 2019. It aims at 1) improving the policy, regulatory and operational environment at national and regional level for the development of regional value chains and related services in the SADC region in agro-processing and pharmaceutical sectors and 2) enhanced participation of the private sector in those value chains, for example by enhancing local manufacturing. The programme has an allocation of EUR 18 million and is implemented through indirect management by SADC (component 1) and GIZ (component 2).

The participation of the private sector, both from the African and the European continent, is also critical in a context of globalized supply chains. The African Health Diagnostics Platform (AHDP) was created by the end of 2018 as a partnership between the Bill and Melinda Gates Foundation, the European Investment Bank and the European Commission. The aim of the AHDP is to significantly improve access and quality of laboratory and diagnostic services for low-income populations in sub-Saharan Africa, contributing to better clinical decision-making, treatment decisions, and quality of care. The AHDP has now been expanded and rebranded as European Health Platform and includes guarantees for both diagnostics and vaccines procured through COVAX. It is also envisaged to support private sector investment in pharmaceutical production under the EFSD+.

Existing African initiatives (PMPA, AMRH, AMA)

The African Union and its Member States have prioritised the pharmaceutical industry over the last 20 years. The Pharmaceutical Manufacturing Plan for Africa (PMPA) endorsed by the AU Heads of State and Government Summit in 2007 identified the importance of strengthening the industry and provided a basis for a raft of different initiatives that have been implemented since to address this complex agenda. The importance of regulatory strengthening and harmonisation was highlighted in the original document and is an area where the most progress has been made. The African Medicines Regulatory Harmonisation initiative (AMRH) launched in 2009 has escorted significant developments on regulatory harmonisation at the REC level and has been the precursor to the envisaged African Medicines Agency (AMA), the treaty for which has now been ratified. Further strengthening and harmonisation of regulatory systems will be essential for increasing access to affordable, effective, safe, quality essential medicines. Europe's experience in building a regional regulatory agency can be invaluable in guiding the process and building the technical capacity for its implementation. The AMRH has been implemented by the African Union Development Agency (AUDA-NEPAD) in collaboration with the national regulatory agencies (NRAs), regional economic communities (RECs), AUC, Pan African Parliament (PAP), the World Health Organization (WHO), the Bill and Melinda Gates Foundation (BMGF), UK Department for International Development (DFID), Clinton Health Access Initiative (CHAI) as a mechanism to address the fragmented regulatory systems as part of PMPA policy framework. It is being implemented in 5 RECs namely, East African Community (EAC), Southern African Development Community (SADC), the Economic Community of West African States (ECOWAS), the Economic Community of Central African States (ECCAS) and, the Intergovernmental Authority for Development (IGAD). Through joint review of dossiers and inspection of manufacturing sites under the AMRH initiative, some regions have witnessed a 50% reduction of timeliness for marketing authorization of medical products. 11 Regional Centres of Regulatory Excellence (RCOREs) have been designated to serve as sustainable structures for increasing regulatory workforce in Africa using existing academic institutions and NRAs. In response to COVID-19 medical supply disruptions, the AMRH Steering Committee endorsed guidelines for regulatory approval, importations and procurement of COVID-19 medical devices, in-vitro diagnostics, and personal protective equipment (PPEs) for use by the AU Member States. The AUDA-NEPAD and WHO as AMRH Joint Secretariat in collaboration with Africa-CDC Initiative composed the Africa Regulatory Task Force (ARTF) to address regulatory barriers on access to COVID-19 vaccine.

In January 2015, the AU Executive Council recognised the AMRH Initiatives as the foundation for establishment of the African Medicines Agency (AMA) in advancing development of the pharmaceutical industry through the PMPA policy framework. The AMA Treaty was subsequently adopted by the AU Summit in 2019 as a Specialized Agency to improve access to quality, safe and efficacious medical products in Africa. The Treaty is expected to come into

force now that 15 Member States have ratified and deposited the instruments of ratification. As of 10.08.2021, 9 countries (Algeria, Burkina Faso, Ghana, Guinea, Mali, Namibia, Rwanda, Seychelles, Sierra Leone) have done so while 6 others (Benin, Cameroon, Gabon, Morocco, Niger, Tunisia) have ratified but not yet deposited the documentation with the AU. 9 other countries have at least signed the treaty already (Burundi, Chad, Egypt, Republic of Congo, Madagascar, Saharawi Arab Democratic Republic, Senegal, Tanzania, Zimbabwe). Whilst there has been universal support for the AMA, the process of ratification has taken significant time and has been achieved in part through the engagement of the AU´s special envoy for the AMA, Michel Sidibé´s activities at the political level. This points to the importance of engaging at the political level to facilitate progress at the technical and institutional levels.

Closer regulatory harmonisation at the REC level has been achieved through the AMRH and this and the advent of the AMA provide a good basis for market defragmentation and investment in the pharmaceutical sector. However, progress on the industry side is lagging that in the regulatory domain, demonstrating that there are other issues that need to be addressed to support development of the sector. The MAV+ initiative will help address non-regulatory barriers to trade in pharmaceuticals and other aspects of the enabling environment in order to support strengthening of the pharmaceutical industry on the continent.

Vaccine development and manufacturing in Africa (PAVM)

The COVID-19 Vaccine Development and Access Strategy endorsed by the AU in August 2020 provides a framework to guide partners' efforts in support of Africa's ambitions. The continental strategy aims to accelerate African involvement in COVID-19 vaccine clinical trials to test safety and efficacy, while strengthening Africa's capacity for running high quality clinical trials. Secondly, the strategy aims to ensure Africa's access to sufficient vaccine supply through financing, procurement and scale-up of vaccine manufacturing. Thirdly, it aims to prepare for at-scale delivery of the vaccine in Africa (including facilitating rapid regulatory decisions and ongoing safety monitoring).

In April 2021, the African Union and Africa CDC launched the Partnerships for African Vaccine Manufacturing (PAVM). In July this year the Africa CDC presented the main strategic lines of the Vaccine Manufacturing Framework for Action in the context of the Agenda 2063 and the African Union's New Public Health Order. PAVM wants to foster the emergence of a local vaccine manufacturing industry in Africa with the aim that 60% of routine and outbreak immunization vaccines will be produced locally and sustainably by 2040. The PAVM bodies are a Task Force, a Secretariat, Work Streams, and an Advisory Group. The main topics for support are: market design and demand intelligence, regulatory strengthening, access to finance, technology and intellectual property, R&D, hubs and talent development, and infrastructure.

3.5 The Intervention Logic

The underlying intervention logic for this action is the following:

1. Advance regulatory convergence, harmonisation and use of reliance mechanisms between regulatory authorities from both continents to address regulatory bottlenecks.

National regulatory authorities (NRAs) play a key role in promoting research and development and local pharmaceutical production whilst controlling the proliferation of falsified and substandard medicines circulating in their respective markets. While supporting national authorities is key, there is a need for regional interventions, particularly in light of facilitating trade of health commodities across countries.

Regulatory convergence represents a process whereby the regulatory requirements across countries become aligned due to the gradual adoption of internationally recognised technical guidance documents, standards and scientific principles, common or similar practices and procedures. The WHO has a mandate to work on regulatory convergence and is currently supporting the existing African Medicines Regulatory Harmonization (AMRH) initiative led by AUDA-NEPAD. This support is critical for the AMRH to evolve in due course into the envisaged African Medicines Agency (AMA), which will operate as a network of national regulatory authorities (NRAs) and regional secretariats in Regional Economic Communities –RECs- (e.g. EAC, WAHO, IGAD, SADC…). The objectives of the AMRH/AMA include joint assessments for granting market authorisation of new or non-registered products, facilitate joint inspections of manufacturing sites, or ensure quality control in production, distribution, marketing and use. Joint work ensures quality and reduces time to perform regulatory functions. The AMRH has relied in funding

from the Gates Foundation and a World Bank Trust Fund so far, meaning that support actions should also tackle the financial sustainability of the future AMA.

The expected **Output under Specific Objective (Outcome) 1** are:

> 1. The African Medicines Agency (AMA) is established and through it regulatory convergence, harmonisation and use of reliance mechanisms are promoted across National Regulatory Agencies (NRAs) and Regional Economic Communities (RECs).

2. Initiate technology transfer and innovation for local production.

Co-led by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO), and supported by UNICEF and the Gates foundation, COVAX is one of the pillars of the Access to COVID-19 Tools Accelerator, a ground-breaking framework for collaboration that brings together governments, health organisations, scientists, businesses, civil society, and philanthropists to speed up efforts to end the pandemic by supporting the development and equitable distribution of the vaccines, diagnostics and treatments the world needs. The initial goal was to secure and deliver 2 billion vaccines doses by the end of 2021, including 1.3 billion vaccine doses for 92 low and middle-income countries. The latter goal was recently raised to 1.8 billion doses, allowing vaccinated population coverage to increase from 20% to 30%. The European Union is one of the main supporters, while the total Team Europe contribution amounted to over € 3 billion.

COVAX has set up a Supply Chain & Manufacturing Task Force. Within it, WHO is establishing COVID-19 mRNA vaccine technology transfer hubs in collaboration with the private sector, academia and entities like the Medicines Patent Pool (MPP). With political support from France and expressed interest by Germany and Belgium, WHO is working with a South African consortium to establish the first hub. The Secretariat or overall coordination and governance structure is yet to be finalised, but a provisional concept and budget has been prepared as a basis for urgent action.

While this objective will build on the opportunities offered by the early stages of the above-mentioned mRNA technology transfer hub, it will be open to the RNA technology but not limited to it exclusively. New technological options may emerge or be considered. Likewise, in principle it will not be limited to SAR-Cov2 vaccines but other products that may get approval from a Stringent Regulatory Authority (SRA) like the EMA in the coming months or years. Although the mRNA technology transfer hub is a key initiative, bilateral deals on mRNA or other technologies fitting the needs and capabilities of African plants may take place beyond that framework. Support to those may be needed and would logically serve to the overall purpose of the action.

The expected **Output under Specific Objective (Outcome) 2** is:

> 2. The mRNA technology transfer hub (or any similar structure promoting health technology transfer ecosystems) is established and adequately coordinates and operationalises technology transfer across Africa.

3. Improved platforms for demand consolidation and strategic purchasing.

Strengthened and expanded vaccine manufacturing capacity in Africa is required to enable the continent's response to the COVID-19 pandemic in the short-medium term and, to increase vaccine security given the recurrent disease outbreaks facing the continent, and in the event of another pandemic or any other potential crises moving forward, in the long term. Uncertainty about the future needs/demand and the resultant risks are a major impediment for investors and point to a range of different scenarios for which the continent must be better prepared in the future. The inherent uncertainties include what volumes of COVID-19 vaccine will be required over what timeframe to bring the current pandemic under control, and what level (if any) of ongoing vaccination against COVID-19 will be warranted moving forward, and utilising which technologies. The timing of a future pandemic cannot be known, nor can the specific technologies and the surge demand required for any future priority vaccine(s). On the other hand, demand for routine vaccinations is more predictable and could provide a lever to encourage investment in and development of enhanced capacity.

The African Union has established the African Vaccine Acquisition Task Force (AVATT) –and the Africa Medical Supplies Platform (AMSP)–, COVAX and its associated Manufacturing Task Force is being co-led by Gavi, CEPI

and WHO, and Gavi currently supports, likewise, the majority of the market for priority routine vaccines, primarily for children. The Partnership for African Vaccine Manufacturing (PAVM) includes these stakeholders and has a specific work stream on demand and market intelligence. The monopsonistic nature of the vaccine market in Africa provides opportunities for a deliberate, coordinated approach to market shaping. However, it is a highly complex undertaking that needs to be aligned with other aspects of the continental strategy such as "push" incentives, technology transfer, and access to finance and removal of trade barriers.

Under Specific Objective 3, the European Commission will support the market demand workstream of the PAVM and the market shaping activities of the COVAX Manufacturing Task Force. It will also actively engage in the ongoing processes to provide its inputs and additional support, whether financial, political or technical, as the need arises.

Demand consolidation and strategic procurement can play an important role for the strengthening of other target industries in Africa, though the market dynamics are very different to vaccines. For essential medicines there are an estimated 600 manufacturers in Africa with virtually all producing finished formulations from imported inputs. Most manufacturers operate in a relatively small range of therapeutic areas, producing generic versions of off-patent products. Many manufacturers need to invest in their manufacturing facilities and systems as well as in product development/acquisition in order to meet requisite international standards. They are hampered from doing so due to a number of systemic challenges including lack of access to affordable finance and the perception that quality is not a commercially successful proposition, as well as fragmented and opaque markets.

Multi-lateral procurement funds such as the Global Fund command significant volumes for specific products against HIV/AIDS, tuberculosis and malaria. Assurance of international quality standards is a prerequisite for supplying such markets, and WHO prequalification of a product is one of the main regulatory mechanisms by which manufacturers can access these markets. Only two companies in Africa have WHO prequalified products so the vast majority of companies cannot supply the international donor funded markets.

Together with pursuing the Specific Objectives 1 and 2, there is a need to defragment markets to facilitate affordable, timely access to quality products. There is also a need for greater market transparency to inform investment decisions. Demand from procurement funds (global health initiatives) can be a means to support leading companies and demonstrate that international standard production is a commercially successful business proposition.

This component builds a solid foundation for the long-term success of a local industry and ensures that locally produced vaccines, medicines and health technologies can enter local markets with competitive pricing models and convincing branding (e.g. to ensure rational use and adherence to treatments).

The **Outputs to be delivered by this action contributing to the Specific Objective (Outcome) 3** are:

3.1. Facilitate platforms for African partners to engage in strategic purchasing and demand consolidation for healthcare products (e.g. the PAVM is setting up a market design and demand intelligence pillar).
3.2. Better understand the demand and pricing dynamics of critical products across the value chain and incentivise European partners to responsibly invest in Africa (e.g. through the analytical work and market shaping activities being conducted by the WHO-backed mRNA technology transfer hub).

4. Enhanced coordination, leadership and programme governance.

Under the leadership and steer of the Commission, this objective aims at ensuring the coherent articulation of all components comprised in this action and future actions in the overall TEI, and will mobilise technical and managerial expertise for capacity development and key support activities (strategic communication and public diplomacy, knowledge management, monitoring, results and impact), including technical support to EU Delegations and better collaboration with the private sector.

Through the coordination objective the Commission will work with stakeholders and partners within the European Union, in Africa and across the international development community to elaborate the approach for strengthening the industry sectors and identify the areas that Team Europe -the EU and its Member States- will support given its comparative advantages versus other donors and partners. The Commission being active in Development, Humanitarian response, Industry, Health, Education and Research and Innovation should be in a unique position to

canvas industry views, build consensus, develop policies and define innovative deal-making models to develop pharmaceutical manufacturing in Africa and vaccines in particular. This dialogue work would form an important component of the overall initiative.

The **Outputs to be delivered by this action contributing to the Specific Objective (Outcome) 4** are:

4.1. Enhanced coordination of all work streams under the TEI (including both national and regional activities) and support to underpin the global leadership role of the EU through a programme support structure which will ensure the EU delivers on its objectives.
4.2. The PAVM Secretariat and the work streams of its strategy are fully operational and in synergy with the TEI.

Further details on the specific activities pursued are provided in section 3.2.

The four Specific Objectives combined are critical interventions to ensure the broader goal of reinforcing African pharmaceutical systems and the regional manufacturing capacity to facilitate access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all, in alignment with SDG 3.8 and in the context of promoting universal health coverage (UHC). These four components will also underpin the regional dimension of the related TEI and its 360° approach.

3.6 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	Indicators	Baselines 2021	Targets 2026	Sources of data	Assumptions
Impact	To facilitate access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all, in alignment with SDG 3.8 and in the context of promoting universal health coverage (UHC).	1. UHC index 2. % of population in Africa with access to essential vaccines / medicines (disaggregated by product, country, location and gender)	To be set by the programme support structure once operative	5% increase (depending on product)	1. WHO Global Health Observatory. 2.World Bank databank. 3. AU 4. Gavi/COVAX.	*Not applicable*
Outcome 1	1. Regulatory convergence, harmonisation and use of reliance mechanisms between regulatory authorities from both continents to address regulatory bottlenecks has been advanced.	1.1. Status of the African Medicines Agency (AMA). 1.2. Number of joint inspections 1.3. Number of manufacturing sites having received Good Manufacturing Practice (GMP) certificates. 1.4. Number of sites having received Good Laboratory Practice (GLP) certificates.	1.1 Not established 1.2 Not established 1.3 - 0 1.4 - 0	1.1 Established 1.2 - 10 1.3 - 3 1.4 - 3	1.1 AU 1.2 WHO / World Bank / AU-PAVM 1.3 AUDA-NEPAD 1.4. TEI structure 1.5. WHO / AU	
Outcome 2	2. Technology transfer and innovation for local production has been initiated.	2.1. Number of technology transfer hubs operative in SSA 2.2. Number of new technologies introduced	2.1 - 0 2.2 - 0	2.1 - 2 2.2 - 1	2.1 WHO/AU-PAVM 2.2 WHO/AU-PAVM	
Outcome 3	3. Improved platforms for demand consolidation and strategic purchasing.	3.1. Number of locally produced health goods (e.g. vaccines) being procured by African or international funds (with EU support)	3.1. - 0	3.1. TBD (e.g. 200 million)	3.1. AU-PAVM	
Outcome 4	4. Enhanced coordination, leadership and programme governance.	4.1. Number of key EU organisations (line DGs, EU MS, etc.) and other initiatives such as PAVM or the COVAX manufacturing task force who are jointly programming or coordinating efforts.	4.1. - 0	4.1. – 3	4.1. TEI implementation structure	
Output 1 **related to Outcome 1**	1.1 The African Medicines Agency (AMA) has been established and through it regulatory convergence, harmonisation and use of reliance	1.1. Number of manufacturing sites having received current Good Manufacturing Practice (GMP) certificates, including decent work standards applied to the pharmaceutical sector.	1.1 – 0 1.2. 0	1.1. – TBD 1.2. TBD	1.1.AU/AUDA-NEPAD/AMA/WHO	

	mechanisms are promoted across NRAs and RECs.	1.2. Proportion of manufacturing sites and administration meeting accessibility standards.				
Output 1 related to Outcome 2	2.1 The Secretariat of the mRNA technology transfer hub (and other similar structures promoting health technology transfer ecosystems) has adequately coordinated and operationalised technology transfer across Africa in the pharma and biotech sectors.	2.1.1 Number of people being trained (disaggregated by sex, age and disability if possible) 2.1.2 Number of African organisations receiving know-how	2.1.1 - 0 2.1.2 - 0	2.1.1 20 2.1.2 2	2.1 WHO/AU-PAVM 2.2 WHO/AU-PAVM	
Output 1 related to Outcome 3	3.1 Platforms for African partners to start engaging in strategic purchasing and demand consolidation for healthcare products have been facilitated.	3.1.1 Increased quality of the transactions (e.g. by volume of goods procured by pooled procurement)	3.1.1 TBD	3.1.1 TBD	3.1.1 AU	
Output 2 related to Outcome 3	3.2 The demand dynamics of all/critical products are understood and European partners are incentivised to invest in Africa.	3.2.1 Number of EU companies initiating operations to manufacture pharmaceutical products locally in Africa	3.3.1 0	3.2.1 2	3.2.1 WHO – AU/PAVM	
Output 1 related to Outcome 4	4.1 Team Europe coordination and global leadership has been enhanced through the creation of a technical programme support structure to deliver on the objectives of the TEI in Africa.	4.1.1 Number of EU Member States jointly programming with the European Commission.	4.1.1 0	4.1.1 3	4.1.1 TEI implementation structure	
Output 2 related to Outcome 4	4.2. The PAVM Secretariat and the African strategy for vaccine manufacturing have been set up, are fully operational and can realise synergies with the TEI.	4.2.1 Number of working groups of the PAVM in which the EU is actively engaged.	4.2.1 0	4.2.1 3	4.2.1 AU/PAVM	

4. IMPLEMENTATION ARRANGEMENTS

4.1 Financing Agreement

In order to implement this action, it is envisaged to conclude a simplified financing agreement with the African Union Commission.

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 entry into force of the simplified Financing Agreement..

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 Modalities

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[10].

4.3.1 Direct Management (Grant)

(a) Purpose of the grant
Together with mobilising an international organisation, specific objective 1 will be supported by an African entity.

(b) Type of Applicant targeted
The Grant is intended as a direct award to AUDA-NEPAD

(c) Justification of a direct grant

Under the responsibility of the Commission's authorising officer responsible, the grant may be awarded without a call for proposal to AUDA-NEPAD in compliance with Article 195(f) of the Financing Regulations due to the level of specialisation of AUDA-NEPAD in this domain. The objective of the existing African Medicines Regulatory Harmonization (AMRH) initiative is to ensure that African people have access to essential medical products and technologies. AMRH is a programme of the African Union (AU) implemented by AUDA NEPAD as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA). The AMRH Secretariat is co-led by AUDA NEPAD and WHO. Gradually the African leadership and ownership should be strengthened. There is no other entity with the same experience and mandate. AUDA-NEPAD is currently in the process of being pillar-assessed and might be eligible for indirect management from early 2022.

4.3.2 Direct Management (Procurement)

The specific objectives mentioned in sections 3.1, 4.1 and 4.2 will be implemented through the procurement of services contracts directly managed by the European Commission. . Objective 4.1 aims at ensuring the coherent articulation of all components under this action and related work streams in the overall TEI, and will mobilise technical and managerial expertise for capacity development and key support activities (communication, EU visibility, knowledge management, monitoring, results and impact), including technical support to EU Delegations and better collaboration with the private

[10] www.sanctionsmap.eu. Please note that the sanctions map is an IT tool for identifying the sanctions regimes. The source of the sanctions stems from legal acts published in the Official Journal (OJ). In case of discrepancy between the published legal acts and the updates on the website it is the OJ version that prevails.

sector. The objectives 4.2 and 3.1 will mainly support the PAVM and also help advance our understanding of demand and market dynamics..

4.3.3 Indirect Management with international organisations.

A part of this action may be implemented in indirect management with an entity which will be selected by the Commission's services using the following criteria: multilateral or regional organisations with sound experience and a mandate to work on regulatory strengthening, sound experience and global leadership in technology transfer in the healthcare context, and convening power. The implementation by this entity concerns specific objective 1, specific objective 2, and specific objective 3.2. This entity will have been fully pillar-assessed before undertaking the responsibilities of indirect management. Section 4.5 on the indicative budget provides a tentative breakdown.

4.3.4 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 4.3.1 is not possible (direct grant), the expected financing could be implemented through indirect management whose details would be further elaborated. Likewise, AUDA-NEPAD is currently in the process of being pillar-assessed and might be eligible for indirect management in the coming months. If this happens, indirect management might be pursued.

If the implementation modality foreseen in section 4.3.2 (procurement) is not possible, indirect management with a Member State or an international organisation could be foreseen.

4.4 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 provisions.

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).

4.5 Indicative Budget

Indicative Budget components	**EU contribution (amount in EUR)**	**Third-party contribution, in currency identified**
Implementation modalities – cf. section 4.3		
Objective 1: Advance regulatory convergence, harmonisation and use of reliance mechanisms between regulatory authorities from both continents to address regulatory bottlenecks, composed of	**16 500 000**	
Indirect management with - An international organisation	11 500 000	
Grant (direct management) with		

- An entity of the African Union in charge of implementing regulatory harmonisation (AUDA NEPAD)	5 000 000	
Objective 2: Initiate technology transfer and innovation for local production, including skills development, consisting of	**12 000 000**	
- Indirect management with an international organisation.	12 000 000	
Objective 3: Improved platforms for demand consolidation and strategic purchasing,	**1 500 000**	
Procurement (direct management)	500 000	
Indirect management with - An international organisation	1 000 000	
Objective 4: Enhanced coordination, leadership and programme governance, composed of	**10 000 000**	
Procurement (direct management) – cf. section 4.3.2	10 000 000	
Evaluation – cf. section 5.2 **Audit** – cf. section 5.3	It will be covered by another decision	N.A.
Totals	**40 000 000**	

4.6 Organisational Set-up and Responsibilities

The programme support structure under Objective 4 will provide technical and logistical support to enhance the governance structure led by the Commission and to implement this action and future ones.

The European Commission being a regional institution itself is uniquely positioned to lead and coordinate the collaborative and complex effort as envisaged in the TEI MAV+. The TEI proposes a concentric circles model whereby people and partner countries are at the centre. At the core of this initiative is also the Commission services (including INTPA and services partaking in an ad hoc project team –SANTE, RTD, JRC, GROW, TRADE, EEAS-), accompanied by Member States (also coordinated through and a Commission-led taskforce) and in coordination with the industry and international partners.

A steering committee gathering representatives from the European Commission, the African Union and EU Member States and partners involved in the implementation of the different components of the action will be set-up and will meet twice a year and advise a smaller executive committee that meets regularly, at least quarterly. Both committees will be supported by programme support structure that will ensure the coordination with other EU and AU actions, notably at national level.

The Commission will also participate in the following taskforces to coordinate the action:

- The PAVM, an important organizational set-up to which this action will contribute. It is supported by a Task Force, a Secretariat, by an Advisory Group in which the European Commission is represented, and has for the time being created 6 working groups.
- COVAX has set up a Manufacturing Task Force.

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 partners 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 from a gender and human rights approach, 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.

Likewise, Commission services in collaboration with the EU Delegations supported by a technical support facility, will be in constant exchange and communication with all project implementing partners to ensure timely implementation of activities and political steering. Commission services shall also assess how the action is contributing to the realization of human rights and the Agenda 2030, and contributing to gender equality, for which SDGs and GAP III indicators will be privileged.

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 external reviews).

5.2 Evaluation

Having regard to the nature of the action, a mid-term and a final external evaluation will be carried out for this action and its components via independent consultants contracted by the Commission. Additional funding from technical assistance facilities will be used.

It will be carried out for problem solving, accountability and learning purposes at various levels (including for policy revision), taking into account in particular the fact that several innovative approaches will be tested in the evolving landscape of African pharmaceutical regulation and production which will produce valuable lessons learnt for the way forward. This evaluation will be undertaken in close collaboration with participating Members States in the TEI

The Commission shall inform the implementing partner at least 60 days in advance of the dates envisaged for the evaluation missions. 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 partner countries and other key stakeholders. 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 evaluation will be gender and human rights sensitive, assess gender equality and human rights results and implementation of rights-based approach working principles (participation, non-discrimination, accountability and transparency).

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.

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 or Headquarters 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[11] (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 4.5, 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	Contribution agreement
☒	Single Contract 2	Direct grant to AUDA-NEPAD
☒	Single Contract 3	Service contract (support and coordination structure)
☐	Group of contracts 1	<foreseen individual legal commitment (or contract) 1> <foreseen individual legal commitment (or contract) 2> <foreseen individual legal commitment (or contract) #>

[11] 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.