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THIS ACTION IS FUNDED BY THE EUROPEAN UNION

ANNEX 2

to the Commission Implementing Decision on the financing of the multiannual action plan in favour of Sub-Saharan Africa for 2023-2025

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 (part III)

MULTIANNUAL PROGRAMME
This document constitutes the multiannual work programme within the meaning of Article 110(2) of the Financial Regulation, within the meaning of Article 23 of the 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 (part III) OPSYS ACT-62011 Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe)
2. Team Europe Initiative	Yes, it supports the access to finance and private sector work streams of the Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa. The Commission works with DE, FR, Belgium and NL in Team Europe approach. NL will contribute with 10 mill EURO to this action.
3. Zone benefiting from the action	The action shall be carried out in Africa, with a particular focus on complementing the efforts of EU Delegations engaged in MAV+.
4. Programming document	Multi-Annual Indicative Programme for Sub-Saharan Africa 2021-2027[1]
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	

[1] Commission Decision adopting a multiannual indicative programme for Sub-Saharan Africa for the period 2021-2027 C(2021) 9373 final of 15.12.2021

6. Priority Area(s), sectors	Human development, health, 120			
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. Other significant SDGs: SDG 1 (reduce poverty) SDG 5 (gender equality) SDG 8 (economic growth) SDG 9 (industry and innovation) SDG 17 (partnerships).			
8 a) DAC code(s)	DAC code 1 – 12110, Health policy and administrative management 70% DAC code 4 – 32168, Pharmaceutical production – 30%			
8 b) Main Delivery Channel	European Union Institutions – 42000 European Investment Bank – 42004 Public entity - 11004			
9. Targets	☐ Migration ☐ Climate ☒ Social inclusion and Human Development ☒ Gender ☐ Biodiversity ☐ Education ☐ Human Rights, Democracy and Governance			
10. Markers (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**
	Biological diversity	☒	☐	☐
	Combat desertification	☒	☐	☐

	Climate change mitigation	☒	☐	☐
	Climate change adaptation	☒	☐	☐
11. Internal markers and Tags:	**Policy objectives**	**Not targeted**	**Significant objective**	**Principal objective**
	Digitalisation	☒	☐	☐
	digital connectivity digital governance digital entrepreneurship digital skills/literacy digital services	YES ☐ ☐ ☐ ☐ ☐	NO ☒ ☒ ☒ ☒ ☒	
	Connectivity	☒	☐	☐
	digital connectivity energy transport health education and research	YES ☐ ☐ ☐ ☐	NO ☒ ☒ ☒ ☒	
	Migration (methodology for tagging under development)	☒	☐	☐
	Reduction of Inequalities	☐	☒	☐
	Covid-19	☐	☒	☐
BUDGET INFORMATION				
12. Amounts concerned	Budget lines **Total estimated cost: EUR 60 000 000** **Total amount of EU budget contribution for 2023: EUR 50 000 000** o 14.020120-C1-INTPA (West Africa): EUR 17 500 000 o 14.020121-C1-INTPA (East and Central Africa): EUR 17 500 000 o 14.020122-C1-INTPA (Southern Africa/ Indian Ocean): EUR 15 000 000 This action is intended to be co-financed by: - The Netherlands for an amount of EUR 10 000 000			
MANAGEMENT AND IMPLEMENTATION				
13. Type of financing	**Indirect management** with Development Financing Institutions (DFIs). This contribution to the African Investment Platform shall be implemented in indirect management by the entities indicated in the annex to this Action Document, in accordance with the Blending Platform's award procedure.			

1.2 Summary of the Action

This Action will contribute to the Team Europe initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (**MAV+**) by enhancing **access to sustainable finance and markets**, and accelerating **private sector engagement**, with a particular focus on local organisations and in view of shared African and European interests.

Considering ongoing and planned actions under the MAV+ scheme, as well as actions of other local and international partners, an important remaining gap has been identified regarding sustainable financing, particularly to unchain private investments and attract solutions from SMEs and start-ups. Likewise, advancing market and needs-oriented research in this domain, and translate the research results into practice, is a strategic priority. Therefore, this 2023 Action proposes to facilitate **access to catalytic financing** as well as to regional **African markets** to **private sector, manufacturers and innovators**. This goal requires the creation of a **specific regional blending project**, which reinforces and is aligned with the specific objectives and needs of the African Union and the Partnership for African Vaccine Manufacturing (PAVM). PAVM's Framework for Action focuses on eight bold programs to unlock Africa's potential to grow and scale vaccine development and manufacturing over the next two decades, and it is currently expanding to other health products. The PAVM includes an access to finance bold programme coordinated by the African Development Bank and Afreximbank, which is open to all DFIs. This action contributes specifically to *Program 2: 'Establishing a manufacturing deal preparation facility and fundraising for ecosystem enablers'*.

Experience has shown that the local production endeavour requires collaboration across several financing institutions. No single major project in Africa is being financed by a single institution, but through the combination of instruments provided by European DFIs, such as EIB, AFD or KfW, African DFIs, and the IFC. This trend will continue, and therefore the EU can play a key role in facilitating that best resources are put in place for the benefit of all, simplifying processes and requirements, and making diversified production of key health products a reality.

At the same time, this action is also aligned and complementary to the renewed market shaping strategies of Gavi or the Global Fund, and potentially able to support the evolution of the World Health Organisation's (WHO) mRNA hub with its various production centres in Sub-Saharan Africa (in South Africa, Kenya, Senegal, Nigeria) and, by extension, the rest of the world (North Africa, Ukraine, Vietnam, Bangladesh, Indonesia, India, Argentina, Brazil, Serbia).

The proposal is consistent with the multiannual indicative programme (MIP) for Sub-Saharan Africa 2021-2027[2], which 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, and it will underpin the health and well-being of future generations. Supporting access to 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 -notably for women and the youth-, facilitate trade, diversify global value chains, engage with the private sector, and reinforce our health, scientific and diplomatic ties with partner countries while advancing universal health coverage (UHC) and human development.

The initial budget for this action is of EUR 50 million (60 including expected additional revenue), with potential to be expanded after its initial phase in view of the evolution of the projects pipeline and the ability of implementers to conclude multi-stakeholder partnership agreements, amplify local production and ensure market absorption.

[2] Commission Decision adopting a multiannual indicative programme for Sub-Saharan Africa for the period 2021-2027 C(2021) 9373 final of 15.12.2021

The intervention logic of this third regional Action (MAV+ III) focuses on two specific objectives –further detailed in section 3 of this document–:

1. **Enhanced financial inclusion of African operators along the pharmaceutical value chain, innovators and manufacturers of essential vaccines, medicines or health technologies that supply African markets and local health systems**.

2. **Improved ecosystem for private sector's full engagement in the development and manufacturing of essential vaccines, medicines and health technologies in Africa.**

It recognises the political imperative of supporting medicinal product manufacturing, 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 health and pharmaceutical systems. The EU differentiates itself from other partners through comprehensive coverage and has a history of applied research and linkages with entrepreneurship. Secondly, the EU seeks full alignment with the African agendas and can drive private solutions to deliver for Africa's challenges and with African partners.

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 1 (poverty reduction, particularly 1.3 protection floor), SGD 5 (gender equality), SDG 8 (economic growth), SDG 9 (industry and innovation), and SDG 17 (partnerships).

This action extensively contributes to **Global Gateway**[3] and the new **EU Global Health Strategy**[4] adopted in November 2022. The action will equally contribute to the carrying out of the EU Gender Action Plan 2021-2025 GAP III[5], in particular to its thematic area of engagement 'Promoting economic and social rights and empowering girls and women'.

2 RATIONALE

2.1 Context

African Union Heads of State and Government launched a call to action in September 2022 to implement the **Africa's New Public Health Order**. Recalling the African Union Assembly Decision of February 2022 that grants autonomy to the African Centres for Disease Control and Prevention (Africa CDC) and the Decision of February 2019 that adopted the Treaty for the establishment of the African Medicines Agency (AMA), there is a strong willingness to focus on: 1. strengthening African institutions for public health, notably Africa CDC and AMA, 2. strengthening public health workforce, 3. **expanding local manufacturing of health products**, 4. increasing domestic investment in health, and 5. promoting action-oriented and respectful partnerships. In addition to the African Union institutions, Regional Economic Communities (REC) also play relevant roles in supporting development efforts. Africa's New Public Health Order emphasises the importance of diversifying global value chains by increasing the share of products manufactured in Africa. The current situation with Africa importing 99% of its vaccines and over 90% of its medicines is not only unfair but it also presents a major challenge to global health supply chains resilience, while leaving in Africa the door open to substandard or falsified products, primarily exported from Asia. Most of the ongoing efforts to address this issue revolve around local production of vaccines, therapeutics (medicines), active pharmaceutical ingredients (APIs), and essential health technologies such as diagnostics.

[3] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway_en

[4] https://ec.europa.eu/commission/presscorner/detail/en/statement_22_3128

[5] The Gender Action Plan III is a Joint communication by the Commission and the High Representative of the Union for Foreign Affairs and Security Policy which was welcomed through EU Presidency Conclusions of 16 December 2020. Drafting was led by European Commission in close consultation with EU Member States, EEAS, civil society organisations, partner governments, and international organisations (UN entities, International Finance Institutions among others). The different parties contributed to the drafting of the document through meetings and through responses to a survey conducted during the process.

During the 6th EU-AU Summit in February 2022, an **Africa-Europe Prosperity Package** composed of an investment package and specific packages in support of health and education systems was announced. The Joint Declaration stated that the health package 'will support initiatives for pandemic preparedness, health security and equitable access to quality essential services'. To deliver on this promise, and in view of Africa's New Public Health Order just described, in early 2023 senior management of the European Commission, Germany (DE), France (FR), Belgium (BE), Sweden (SE) and The Netherlands (NL)[6] agreed to establish a joint **High Level Steering Committee** (HLSC) with African partners to drive common objectives in health, starting with the Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in an initial phase. Consequently, the European Commission has proposed to the Africa Union Commission (AUC) and the Africa CDC to establish a **streamlined steering and coordination structure for health-related flagships and their respective Team Europe Initiatives (TEIs)**, complementing existing political, diplomatic and technical structures. This proposal will accomplish two objectives:

1. Leaders in global health from both continents are engaged in a mutually beneficial partnership. Strategic engagement of African counterparts with partners following a Team Europe approach (including European Commission, Member States and European DFIs) is necessary for a shared ownership of health initiatives and sustainable results.

2. Effective coordination of partners. A joint steering mechanism for health related TEIs/Flagships will facilitate coherent decision making, focus on delivering concrete results, and the division of labour across partners, while respecting the singularities of each member and each health topic.

The HLSC will ensure co-creation of **MAV+** between Europe and Africa, building bridges between MAV+ and PAVM. Announced in May 2021, in two years MAV+ has become a Flagship under Global Gateway and a Presidential priority whose ultimate objective is increasing equitable access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all Africans, in line with SDG 3.8. Its main objective is not only to scale up production but also to remove all access barriers. It is an initiative that, on the one hand, is linked to the efforts to be better prepared against future pandemics and, on the other hand, focuses on strengthening pharmaceutical and healthcare ecosystems. To ensure both impact and sustainability, its policy framework follows a comprehensive, **360-degree approach**, encompassing **three key dimensions** –a) supply side, b) demand side, and c) the enabling environment. It revolves around **6 work streams**: 1) industrial development, supply chains and private sector, 2) market shaping, demand and trade facilitation, 3) regulatory strengthening, 4) technology transfer and intellectual property management, 5) access to finance, 6) R&D, higher education and skills. It encompasses national and regional level interventions.

Prior to this regional Action (MAV+ III), MAV+ I and MAV+ II put an emphasis on advancing African leadership in this domain, improving coordination in a Team Europe approach under a common framework, regulatory strengthening, and technology transfer with a focus on the mRNA platform. Consequently, at **continental level** the Commission is supporting the two main African public health agencies: the existing Africa Centers for Disease Control and Prevention (AfCDC) -which hosts the secretariat and programmes of the Partnership for African Vaccine Manufacturing, PAVM- and the establishment and operationalisation of the African Medicines Agency (AMA) . Likewise, the EU is contributing to the efforts of AUDA-NEPAD to continue advancing the African Medicines Regulatory Harmonisation (AMRH) initiative at country, regional and continental levels. Another important existing implementing partner is WHO.

At **national level**, the EU Delegations and actors in a Team Europe approach are active in Senegal, Rwanda, South Africa and Ghana, and since more recently in Nigeria. A summary of the situation in each country is provided below.

Senegal
The MADIBA project promoted by the 'Institut Pasteur de Dakar' (IPD) and co-financed by partners following a Team Europe (TE) approach is expected to launch production of new vaccines in 2024. IPD already produces yellow fever vaccines and Senegal is a partner ('spoke') of the mRNA technology transfer programme managed

[6] INTPA's DDG and representatives from Ministries of international affairs or development cooperation. EU MS implementing agencies were also present.

by WHO in partnership with the Medicines Patent Pool (MPP). Senegal will also launch in 2023 the Centre for Africa's Resilience to Epidemics (CARE), financed by the European Commission. BioNTtech, planning investments in the country, signed a MoU with IPD for the production of vaccines. Bill and Melinda Gates Foundation funds R&D through Univercells and Batavia. Beyond IPD, the national pharmaceutical strategy elaborated in November 2021 to reach pharmaceutical sovereignty has been costed by the government at EUR 500 million and TE has committed around EUR 155 million so far, including for example support to MADIBA -with EIB as lead financer- or the National Regulatory Authority.

Rwanda
BioNTech plans to produce drug substance starting in 2024 with BioNTainers: modular factories arriving in the second part of 2023 to help produce novel vaccines. BioNTech signed a power purchase agreement with Izuba Energy Ltd, which will build a solar plant limiting the carbon footprint of vaccine production. Contributions in a Team Europe approach amount to EUR 22 million, focusing on strengthening the regulatory environment (working with the Rwanda Food and Drug Authority) and the skills supply (MSc and PhD at University of Rwanda, etc.).

Ghana
A Presidential Vaccine Manufacturing Committee has been set up and Parliament passed this year the National Vaccine Institute bill to oversee research and manufacturing. DEK Vaccines Limited is setting a fill & finish facility in the first quarter of 2023 with production expected in 2025. The country has estimated its financial needs at USD 200 million. TE current allocation is EUR 15.9 million. Ongoing TE contribution is supporting the Ghana FDA (regulator) and DEK.

South Africa
The private holding Aspen Pharmacare obtained EUR 600 million long-term financing with over 50% of it from TE. Production of COVID-19 vaccines at Aspen licenced by J&J already started. Demand has been low as vaccine donations have curtailed an already weak roll-out capacity by countries. A new agreement with the Serum Institute of India will allow to use the same capacities to produce other vaccines commonly administered in Africa (pneumococcal, polyvalent, meningococcal or rotavirus vaccines). A second manufacturing project is with Biovac, a public-private partnership aiming to provide fill & finish capacity for Pfizer, and ensure end-to-end production as spoke of Afrigen (WHO's mRNA hub). Production dates are not confirmed. TE has mobilised over 400 million in South Africa (e.g. including support to SAHPRA, the regulator).

Nigeria
In December 2022 EIB signed a 14 million loan with Emzor from Nigeria for production of active pharmaceutical ingredients, including for treatments against malaria. While not among the first four countries, it has potential given its market size and its already booming industry. According to the National Agency for Food and Drug Administration and Control (NAFDAC), as of 2021 there were over 150 pharmaceutical manufacturing companies operating in Nigeria.

A number of additional African countries have expressed their interest in pharma production (to the EU or in other fora), namely Kenya, Zambia, Tanzania, Guinea, Mozambique, Mauritius, Zimbabwe (INTPA countries), Egypt, Tunisia, Algeria or Morocco (NEAR countries, outside the scope of this AD). The **decision on whether to support or not new projects** in new countries will depend on multiple factors, including the country ownership and leadership, the existence of a robust business case, public health needs, and sustainability. The priority for now remains accompanying the frontrunners and ensuring sustainability and uptake, while at the same time this regional action could also accommodate a few new projects in Sub-Saharan Africa.

Thus, in view of the above, MAV+ extensively contributes to **Global Gateway**[7] and the new **EU Global Health Strategy**[8] adopted in November 2022. It is also aligned with the **Pharmaceutical Strategy for Europe**[9] and complements the **EU4Health**[10] programme and **Horizon Europe**[11] (notably the joint undertaking Global Health -

[7] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway_en
[8] https://ec.europa.eu/commission/presscorner/detail/en/statement_22_3128
[9] https://health.ec.europa.eu/publications/pharmaceutical-strategy-europe_en
[10] https://health.ec.europa.eu/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en
[11] https://commission.europa.eu/funding-tenders/find-funding/eu-funding-programmes/horizon-europe_en

European and Developing Countries Clinical Trials Partnership, GH-EDCTP3 JU[12]). Commission services cooperate and coordinate on MAV+ and the AU-EU broader partnership in health. Further synergies and complementarities with the actions of other Commission services will be taken into account to maximise coherence and impact.

In order for the European Union to become a reliable partner for Africa, MAV+ must build on bilateral initiatives of **EU Member States** as well. Current EU MS support in the form of grants puts an emphasis in areas such as policy development, regulatory strengthening (assistance to African medicines regulators), skills and capacities. Nevertheless, gaps remain notably when it comes to facilitate the participation of the private sector. The main drivers of support to private operations are being financing institutions (details under the section 'main stakeholders' of this document).

2.2 Problem Analysis

To better understand the problems and start identifying solutions, the European Commission has established a continued dialogue with key African, European and international partners. The 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. While non-communicable diseases are on the rise, infectious diseases such as malaria, tuberculosis or HIV-AIDS are still prevalent. The disruption in the supply chain and technologies for sexual and reproductive health caused a disproportionate increase in maternal mortality, especially among adolescents. Sub-Saharan Africa maintains the highest maternal mortality ratio in the world.

Both local manufacturing –targeted by this initiative- and the need for broadening and diversifying global value chains open opportunities for Africa's industrial development and contributes to improve access to the essential health products. Developing manufacturing capacity for medicines and other health products therefore represents an opportunity to advancing the right to health, improving resilience, and promoting inclusive development in Africa. However, improving local production and access to vaccines, medicines and health technologies in Africa is hampered by multifaceted barriers:

A. Limited access to finance.

Whereas MAV+ I (financing decision from 2021) and MAV+ II (financing decision from 2022) are improving the regulatory environment, facilitating technology transfer and boosting African leadership, and EU-led country level actions are advancing other domains like national regulatory strengthening or tertiary and TVET education, access to finance is critical for the growth and sustainability of local biotech, pharmaceutical and health technology production in Africa. There are several reasons why this is the case:

1. Research and development: Developing new drugs and treatments is a long and expensive process that requires significant investment. Without access to finance, African biotech and pharma companies may struggle to conduct the necessary research and development to bring new products to market.

2. Manufacturing capacity: Manufacturing biotech and pharma products at scale requires substantial investment in equipment, facilities, and personnel. Access to finance is essential to build and maintain the necessary manufacturing capacity to meet demand and ensure the quality of products.

3. Regulatory compliance: Meeting regulatory requirements for drug approval and safety is a complex and expensive process that requires significant financial resources. Access to finance is essential to ensure that African biotech and pharma companies can navigate these requirements and meet the necessary standards.

4. Market access: Expanding into new markets -notably intra-African trade across the continent- and reaching more patients requires investment in marketing, distribution, and sales channels. Access to finance is essential to build the necessary infrastructure and networks to reach new markets and expand access to life-saving drugs and treatments.

[12] https://research-and-innovation.ec.europa.eu/research-area/health/edctp_en

Improving access to finance for African biotech and pharma companies can help to overcome these challenges and support the growth and sustainability of the industry. This can be achieved through a combination of public and private financing, including government and donors grants, private equity, and venture capital, and the availability at regional level of a pool of expertise in conducting businesses.

Limited access to finance can by analysed through different angles:

a) Cost of capital and uncertain economic returns of local pharma, biotech and medtech production.

African manufacturers and European and global partners have listed the **cost of capital** on the continent and the **uncertain economic returns** as a significant challenge in setting and scaling up manufacturing facilities in Sub-Saharan Africa. While EU grants in various forms are currently contributing to underpin the enabling ecosystem for local production (section 2.1 above), the complex nature of projects, the associated risks, and the high financial allocations needed to succeed require a stronger EU partnership with European and African financing institutions, as well as offering concrete incentives to the private sector (predominantly not-for-profit and socially responsible organisations) and innovators (including public institutions such as academia and research centres) that are developing industrial applications. Therefore, the *conditio sine que non* to succeed in diversifying global value chains, building a portfolio of diversified projects with regional and continental relevance, and be able to sustainably manufacture quality health products in *Africa for Africa* is **making catalytic financing available** for project preparation, obtaining market intelligence, de-risking loans and making them more affordable.

Substantial funding has been made available under MAV+. Over EUR 1.1 billion has been allocated so far to projects by European donors and **development financing institutions (DFIs)**. DFIs collectively have made available around 70% of the TEI resources primarily via loans to Institut Pasteur Dakar (Senegal), Aspen (South Africa), Emzor (Nigeria), and more operations are being shaped (not confirmed) with Akagera (Rwanda), DEK (Ghana), Biovac (South Africa), and potentially others. Therefore, DFIs are indispensable partners considering the scale of the investments. In the case of the European Commissions' contributions, currently most of EU funding is in the form of grants from NDICI-Global Europe (predominantly regional funds), and on top of this there are other smaller sources from the EU budget such as Horizon Europe (i.e. call for proposals).

b) Pervasive funding needs for the broader ecosystem to ensure access to health products.

Despite substantial EU contributions to this agenda, unparalleled to other traditional donors (US, UK, etc), the AU identified an **existing funding gap** of USD 30 billion in the Framework for Action under the Partnerships for African Vaccine Manufacturing (PAVM) to reach the target for Africa to produce 60% of its own vaccine needs on the continent by 2040. This encompasses 80% of operating expenses. The methodology used emphasises R&D gaps (20 billion), inter alia. The African Development Bank estimates a EUR 11 billion gap in order to locally produce 70% of the critical health commodities to meet the public health needs. With this in mind, and while several actors and not only donors will have to contribute, there is room to widen EU contributions.

c) Need to unlock public and private resources, and various EU financing instruments, to improve overall financing of the health systems and deliver solutions.

While the EU should play its part as key donor, and tag additional resources from DFIs, the financing matrix equality requires **public domestic resources**, particularly to ensure predictable demand for locally produced goods, and -importantly- **private sector** investments.

Globally, 50 to 90% of expenses for health products are covered by patients and their relatives. In LMICs, medicines represent up to 60% of household expenditure in health, compared to 18% in OECD-countries. This is an inequitable mechanism as poorer households spend proportionally more than others. Health products should be equitable, ensuring that their access, quality, availability, and affordability do not vary in on account of gender, disability ethnicity, geographic location, and socio-economic status; and that the specific constraints and needs of the most vulnerable are taken into account.

In Africa a risk exists that the pharmaceutical market could mainly serve private and for-profit infrastructures, only marginally reaching the most vulnerable and thus increasing inequalities. Greater investment by governments in their health social protection systems would help to address this challenge.

There are positive signs about the private sector involvement. Production facilities of BioNtech (EU, DE) are being established in Rwanda and the company is exploring other countries (Morocco, South Africa, Senegal, Ghana). Moderna (US) announced an investment of USD 500 million in Kenya. Another prominent company is Univercells (EU, BE), with main projects in Senegal, South Africa or Kenya, and a specialisation in equipping the manufacturing plants with innovative, affordable, modular technology. Big pharmahas been present for years in Africa, yet with a primary focus on mere distribution and sales, but technology transfer through voluntary agreements is growing (i.e. Sanofi -FR- with Biovac in South Africa). Other important actors are Contract Development Manufacturing Organisations (CDMOs), for example Recipharm (SE), and manufacturers of more traditional equipment for viral vector vaccines.

Available data indicate that while big international corporations are able to invest their own resources, that is not the case for the emerging local companies and possibly for new, innovative European partners interested in developing businesses in Africa. 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 99% of its vaccines) and is reliant on other regions for virtually all inputs (e.g., active pharmaceutical ingredients –APIs–, excipients, bottling, packaging) for local production. 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, increasing regional inequalities and compounding an already tragic situation.

Under EU and AU leadership, and in partnership with the private sector, European, African, and International financing institutions, private banks and investment funds, the EU will nurture financing opportunities and vehicles to fund the establishment or expansion of infrastructures needed in the biotech, pharma or healthcare technology sectors in Africa, as well as to improve access to markets and defragment the demand side. The EFSD+ investment windows –particularly the new Human Development Window- could incentivise and de-risk investments and promote public-private partnerships in the pharmaceutical, biotechnology and health technology sectors. However, with the current state of play, guarantees alone for MAV+ related projects would be insufficient to finance complex undertakings. The true potential of innovative financing for the pharma and biotech sectors is being unlocked through this proposal which decidedly resorts to grants and blended finance with a view on impact and sustainability. Thus, the proposed financing instrument will be one to complement and unlock other financing instruments.

B. Limited availability, accessibility, acceptability and affordability of health products of assured quality.

Due to obstacles in accessing medicines and health products of good quality, affordable and in a timely fashion, the full enjoyment of the right to health remains an elusive goal for millions of people around the world, particularly children and women. It is estimated that 2 billion people, many of whom are living in Africa, do not have access to safe and effective essential medicines and other health products. On average, 10.5% of the medicines used in Low and Middle-Income Countries (LMICs) are sub-standard or falsified (SSF). Good Manufacturing Practices (GMPs) remain a challenge.

Equitable access to health products is a global priority and should be a global public good. The availability, accessibility, acceptability, and affordability of health products of assured quality is essential to the achievement of the Sustainable Development Goals, in particular targets 1.3, 3.8 and 10.4. There is a need for new and appropriate quality products addressing specific pathology existing on the continent and validated in relevant environmental and populations conditions, therefore adapted technology transfer and local innovation responding to real needs are needed and have to be supported from the beginning. Every disease management strategy requires access to health products for prevention, diagnosis, treatment, palliative care, and rehabilitation. Primary health care (PHC) services rely on access to health products, including medicines, vaccines, medical devices, diagnostics, protective equipment, and assistive devices. These products must be of assured safety, efficacy, performance, and quality, available and affordable. The risk of poor-quality medicines remains a major threat to patients and economies.

Therefore, strengthening local manufacturing of and thereby improving access to quality vaccines, medicines and medical technologies and assistive devices 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, regional organisations, and the most vulnerable to put in place policies and enforcement measures to organise the sector.

C. Demographic pressure.

The African continent is today home to 1.3 billion people and accounts currently for 25% of the global disease burden. Moreover, by 2050 the population is expected to have reached at least 2 billion people. By 2050, the youngest subgroup (ages 0–14) is projected to double to about 685 million. The working age population (ages 15–64) is projected to triple to 1.25 billion.

Therefore, demand of healthcare will increase in proportion for each age group. The African biotech, pharma and health technology markets have significant growth prospects, but there are also challenges that must be overcome to achieve their full potential. On the positive side, Africa has a growing population and a growing demand for affordable and accessible healthcare. Additionally, the continent is home to a rich biodiversity that can be tapped for novel drugs and treatments.

D. Multidimensional barriers to access that require concerted, 360-degree action

To help address the many barriers, the broader Team Europe Initiative (TEI) is leveraging resources from the European Commission, European financing institutions and EU Member States. As indicated, an integrated, multi-layered and comprehensive support package is tackling barriers to manufacturing and access to health products and technologies in Africa from different angles and is placing the continent's own actors and institutions at its heart. MAV+ framework revolves around 3 dimensions –a) **supply side**, b) **demand side** and the c) **enabling environment** for health and pharmaceutical systems– and 6 work streams: 1) industrial development, supply chains and private sector, 2) market shaping, demand and trade facilitation, 3) regulatory strengthening, 4) technology transfer and intellectual property management, 5) access to finance, 6) R&D, higher education and skills.

a) The **supply side (1)**
- Industrial development.
- Supply chain management and integrity (e.g. with digital tools).
- **Private sector engagement.**
- 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 other health products, and a modern mix of quality-assured SRH-commodities.

b) The **demand side (2)**
- 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.
- Trade facilitation (reduce tariff and non-tariff trade barriers for the movement of raw materials and finished products across the continent).

c) The **enabling environment and pharmaceutical / health systems**
- Regulatory strengthening. 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. (3)
- Technology transfer and intellectual property management (4).
- **Access to finance**, establishing financing vehicles and instruments de-risking private investments, domestic resources. (5)
- R&D, higher education and skills. Promotion of human capital development. (6)

Main stakeholders

This agenda involves numerous stakeholders at multiple levels across different domains. Achieving the health objectives requires coordinated action between all partners in order to fill gaps and avoid overlaps.

First, African institutions must drive the agenda and coordinate financial and technical partners. The Commission has established a solid collaboration with the Partnerships for African Vaccine Manufacturing (PAVM) which includes, as part of their bold programs, an access to finance work stream. It is led by African Development Bank and Afreximbank. The overall Partnerships for African Vaccine Manufacturing (PAVM) is coordinated by the Africa CDC.

Second, special attention deserves the private sector. There are dozens of vaccine manufacturing projects and above 600 pharma manufacturers in Africa (to mention a few, Aspen Pharmacare in South Africa, Hikma Pharmaceuticals in Sudan and Egypt, Fidson Healthcare and Pharmanova in Nigeria, Bionex in Ghana, etc.). These numbers are expected to grow and multiply the opportunities. Comparatively, according to a report by the European Federation of Pharmaceutical Industries and Associations (EFPIA), there are approximately 4,500 pharmaceutical companies in Europe, including both large multinational companies and small-to-medium-sized enterprises engaged in pharma and other health products. In Asia, there are also a large number of pharmaceutical companies. According to GlobalData, there are over 20,000 pharmaceutical companies in Asia, with the majority of them based in India and China. Although the market has failures, public actions must respect market dynamics and fair competition. To benefit from MAV+ III, specific requirements will be applied (please refer to section 4.3), such as the existence of a public health interest and the priorities addressed (scientific, medical, geographical, missing products, etc.), the sustainability of the proposal (solid concept and business plan, appropriate human and technical capacities, socio-economic impact), as well as equity, quality, transparency and fair pricing parameters.

Third, financing institutions are indispensable partners. European DFIs are extensively contributing to MAV+, yet the multiplication of funders (European, African and international), each with different approval and disbursement requirements, adds extra layers of complexity to projects. For this reason pooling resources and lowering transaction costs is so critical. The list includes European financing institutions (EIB, EDFI including AFD group -AFD, Proparco-, KfW group -KfW, DEG-, FMO, Belgian Investment Company for Developing Countries -BIO- and others), African financing institutions (African Development Bank and Afreximbank), World Bank Group (notably IFC), the U.S. International Development Finance Corporation (DFC) or the Islamic Development Bank.

EIB has several projects in the pipeline in various countries and has reported the signature (June 2022) of a EUR 75 million loan to Institut Pasteur de Dakar (IPD) in Senegal (MADIBA project). It has also approved a 14 million loan to a Nigerian company, Emzor, for the production of antimalarials. The EIB pipeline includes: South Africa (further support to Biovac in collaboration with EUD and Gates -on cholera-), Rwanda (Akagera, researching on tuberculosis), Nigeria (exploring a partnership with Innovative Biotech Nigeria Limited), Senegal (IPD), and Ghana (DEK). All these projects will require clinical development as are based on products that are not yet ready for the markets.

EIB, AFD and KfW have signed separate agreements with Afreximbank. The African Development Bank together with Afreximbank lead the access to finance pillar of the PAVM.

Other stakeholders include the AU Commission, AU Member States (who procure health products), AUDA-NEPAD, Gavi, the Global Fund to Fight AIDS, tuberculosis and malaria, WHO, the Medicines Patent Pool (MPP), the Gates Foundation, GH-EDCTP JU, the EU-Africa Innovation Agenda other multilateral and global health initiatives, patients' groups and civil society organisations.

Gavi is proposing a new time-limited financial instrument that can help mitigate the high cost of vaccine production at market entry. Such instrument under preparation may require both grants and guarantees, as well as bank resources. At the time of drafting this AD, the mechanism is under construction.

3 DESCRIPTION OF THE ACTION

3.1 Objectives and Expected Outputs

African manufacturers and European partners have listed the cost of capital on the continent and the uncertain economic returns as a significant challenge in setting and scaling up manufacturing facilities in Sub-Saharan

Africa. While EU grants in various forms are currently contributing to underpin the enabling ecosystem for local production (section 2.1 above), the complex nature of projects, its associated risks, and the high financial allocations needed to succeed require a stronger EU partnership with European, African and global financing institutions, as well as offering concrete incentives to the private sector (predominantly not-for-profit and socially responsible organisations) and innovators (including public institutions that are developing industrial applications based on academic research).

The **Overall Objective (Impact)** of this action is increasing **equitable access to safe, effective, quality and affordable essential health products[13] for all Africans**. This objective pursues SDGs 3.8 and 10 and promotes ultimately universal health coverage (UHC). Its attainment requires reinforcing African pharmaceutical systems.

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

1. **Enhanced financial inclusion of African operators along the pharmaceutical value chain, innovators and manufacturers of essential vaccines, medicines or health technologies that supply African markets and local health systems.**

This expected outcome is linked to ensuring that essential vaccines, medicines and health technologies reach African markets and are available in local health systems. The *conditio sine que non* to succeed in diversifying global value chains and be able to manufacture health products in *Africa for Africa* is making catalytic financing available for project preparation, obtaining market intelligence, de-risking loans and making them more affordable. This component proposes the creation of a Thematically Focused Blending Project under the African Investment Platform that will make available non-refundable resources to incentivise sustainable production and potentially acquisition of vaccines, medicines and health technologies in Africa by filling the gaps not satisfied through other available resources such as EU guarantees and bank's own resources. The advantages of a regional solution are: 1) having one assistance mechanism that pools expertise for various countries and projects, 2) having a portfolio approach to spread the overall risks, and 3) allowing a regional value chain or network approach (resilient production requires that the production nodes are somehow interchangeable, and components of a product may be sourced from different countries). The proposal shall reduce project cost to end users or taxpayers (when governments are involved) by reducing total investment in local manufacturing. It can also make African producers more competitive. Access to quality, effective, safe and affordable essential health products and technologies will be expanded. New products will be made accessible, available and affordable for the African population with a focus on the most vulnerable (bottom poorest 40%).

Several financing institutions have confirmed their interest in this proposal, having a pipeline of projects for a diverse range of products that could be implemented starting in the second half of 2024. Countries to host these projects may include tentatively Rwanda, Ghana, Senegal, South Africa, Nigeria or Kenya. This is a non-exclusive list and shall not impede exploring possibilities in other countries where health is a priority for EU health cooperation, notably to ensure equitable access. A single blending proposal is expected with a regional or multi-country dimension.

2. **Improved ecosystem for private sector's full engagement in the development and manufacturing of essential vaccines, medicines, and health technologies in Africa.**

This component will contribute to identify promising new health solutions in the health products and technologies domain, and make them accessible, available and affordable for the African population. The objective is incentivising such solutions by improving the ecosystem, not only through a mere regulatory perspective (covered through ongoing actions) but rather by advancing other fronts like the predictability and completeness of health laws, adequate pricing practices and reimbursement policies, or transparency in R&D costs.

The expected **Outputs under Specific Objective (Outcome) 1** (enhanced financial inclusion of African operators along the pharmaceutical value chain, innovators and manufacturers of essential vaccines, medicines or health technologies that supply African markets and local health systems) are:

[13] When the document refers to health products, it should be understood that health technologies (including assistive technologies), commodities, devices, medicines and vaccines are included.

1. Increased catalytic/de-risking funding opportunities to pharmaceutical and associated companies, particularly local ones and SMEs, alone or in partnership with the public sector, linked to the production of treatments for infectious diseases of high prevalence in Africa as well as for neglected tropical diseases. Consequently, regional -and global value chains- for health products are diversified, competitive and resilient.
2. Improved dissemination of evidence and knowledge about African countries' public health needs.
3. Expanded pipeline of relevant, viable and bankable projects in alignment with the PAVM's vision and MAV+ access to finance work stream.
4. Increased availability of market intelligence and business opportunities for the pharma, biotech and health industries in Africa.
5. Increased resilience of manufacturing facilities in the continent.
6. Increased availability of health products locally and sustainably produced, resulting in African products, are procured to meet African demand (disaggregated by health application, age group, gender, and when possible, disability, income and place of residence targeted)

The **Outputs** to be delivered by this action contributing to the **Specific Objective (Outcome) 2** (Improved ecosystem for private sector's full engagement in the development and manufacturing of essential vaccines, medicines and health technologies in Africa) are:

1. Increased development and validation of affordable new solutions in the health products and technologies domain (i.e. new vaccines, medicines or diagnostics) for the African population, building on existing initiatives and knowledge.
2. Increased understanding of legal requirements to operate including for market authorisation, WHO prequalification, technology transfer, management of intellectual property or good manufacturing practices (GMPs).
3. Improved knowledge sharing on adequate pricing policies, particularly those directly and voluntarily applied by companies.
4. Improved knowledge sharing on effective reimbursement policies by governments.
5. Improved mechanisms and tools for transparency in R&D costs and cost components, notably for those companies obtaining public EU benefits.
6. Higher market intelligence and data on market actors and market failures, and better understanding of inequality drivers (i.e. across population groups and countries).
7. Strengthened public-private dialogue, engagement and collaboration.

3.2 Indicative Activities

Activities related to Output 1 (non-exhaustive)

1.1. Conceptualisation of the platform in close collaboration with PAVM and DFIs.
1.2. Project preparation is done in a collaborative way allowing financial partners to pool resources and better share high quality technical expertise, decreasing transaction costs for project owners and clients.
1.3. Technical assistance is pooled for project preparation and overcome market failures, in alignment with the PAVM's vision and MAV+ access to finance work stream.
1.4. Essential supplies or molecules whose production is still limited or insufficient will be mapped and regularly updated, with a particular focus on infectious diseases of high prevalence in Africa (HIV/AIDs, tuberculosis, malaria, etc.) as well as neglected tropical diseases. This activity will be carried along the priorities identified under the Africa CDC 'Risk Ranking and Prioritisation of Epidemic-Prone Diseases'.
1.5. WHO pre-qualification for African manufacturers is facilitated, building on existing EU-WHO partnership and this project.
1.6. Gavi eligibility for African manufacturers is facilitated, building on existing EU-Gavi partnership.
1.7. Provide better access to catalytic finance and markets for pharmaceutical and health products industries, including local ones and SMEs. The concrete tools will be specified in the contribution agreement and may include some of the following instruments. First, specific components of projects (CapEx, OpEx or premiums) may be covered in the form of investment grants when duly justified by their development impact. The allocation will allow to implement projects by offering grants for capital or operational

expenditures, or a resilience premium to select new manufacturers, depending on the concrete needs. Second, revolving grants could also be considered, for example for SMEs, innovators and new entrants in case they obtain benefits. Third, own resources from financing institutions (conditional loans, equity), private investors and governments are expected to be equally mobilised for the projects under the platform. Finally, although not a priority, other de-risking tools could be assessed and used if well justified (export credit guarantees, interest rates subsidies).

1.8. Identify and promote synergies with ongoing research initiatives and networks, such as the EDCTP. This may include supporting the development and completion of clinical trials and studies needed for validating and assessing health products, in cases where there is a strong potential to put the new products into the African markets.

1.9. Scaling-up validated innovation in healthcare, including implementation research and innovation procurement;

1.10. Adapting transferred technology to fulfil the environmental or societal requirements (local, regional or continental conditions).

1.11. Social and economic returns to investments will be evaluated.

1.12. Create 'push' incentives (e.g. through this blending project) in a way that they can be complemented by 'pull' incentives (e.g. through volume guarantees or advanced purchase agreements covered by EFSD+).

Activities related to Output 2 (non-exhaustive)

2.1. Analysis of promising private sector companies, initiatives, products, technologies and innovations able to respond to existing public health needs.

2.2. Facilitate access to information on legal and regulatory requirements, in many cases not readily available.

2.3. Development of different incentives to ensure that the private sector adopt fair prices, particularly for the most deprived and poor populations.

2.4. Mechanisms to promote price transparency will be set up.

2.5. Expansion of classic bilateral government-to-government cooperation, for example by mapping existing tools and methods to promote trade and private sector activities in low-and middle income countries and link them with development assistance (i.e. usual activities of chambers of commerce or EU trade services such as organisation of business missions, participation in trade fairs abroad, market studies, matchmaking and marketplace opportunities, etc.).

2.6. Collaboration between private sector and authorities will be reinforced, with a view to overcome trade and legal bottlenecks or uncertainties.

2.7. Market research and data analysis will help better understand market dynamics and health inequality drivers (i.e. across population groups and countries) and close data gaps.

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, should they take place.

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 women, adolescent girls and children particularly in times of scarcity and in fragile settings, with weak health systems. Reducing scarcity and improving availability of crucial health products like the COVID-19 vaccine and other routine vaccines, and the availability of SRHR products, has thus a direct impact on women's and children's lives.

Likewise, women are a significant majority among first line healthcare workers. Today women account for 70% of the health and social care workforce and deliver care to around 5 billion people. But women remain largely segregated into lower-status and lower-paid jobs in health, are subject to discrimination and, in some contexts, are under the constant threat of violence. Despite women being 70% global health workforce, they hold only 25% of senior roles. This Action is a real opportunity to contribute to reducing gender inequalities in the industry sector. In SSA, only 8,6% of women employed are in the industry sector[14]. As such, women will be part of the leaders promoting the manufacturing and access to quality health products agenda. In settings where cultural barriers prevent women from accessing decent jobs in these sectors, initiatives to increase the number of female employees at different positions could be supported.

The action contributes to the Gender Action Plan III (GAP III, 2021-2025), more specifically to its 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 health interventions are developed by international organisations (UN Women, UNDP, WHO) and can be helpful during implementation of the action.

Human Rights

Access to the highest attainable health is a human right which requires real access to quality, safe, accessible, affordable and effective health products. Human rights principles will be central in the implementation of the action. Populations in countries with lower manufacturing capacity are also going to benefit from the outcomes of this action, as one of the overarching objectives is equitable access to health products and technologies continentally. Particular attention will be paid to ensuring full respect for human rights and equal treatment of all.

Disability

This action is labelled as D1. Persons with disabilities, patients with long-term health conditions and older persons (particularly in rural areas) will benefit especially from the improved availability and quality of quality health products in Africa. Support to local production of pharmaceutics essential to persons living with disability such as for epilepsy, tranquilisers, relaxants for spasms, as well as of assistive technologies (wheelchairs, hearing aids, prosthetics, glasses, etc.) will be considered. According to WHO, currently, only about 15% to 25% of people in need of assistive products have access to them. While there is a large unmet need for all types of assistive products in the WHO African Region, the actual coverage levels of these products are not proportional to the prevalence of impairment types. Through this Action, the European Commission will work with national and international partners to facilitate the access, availability, quality and safety of health products and essential assistive technologies necessary for empowerment of persons with disabilities in the region. The action will also pay particular attention to facilitate participation of persons with disabilities in the skills building, training activities, consultations and in created employment opportunities. Accessibility to information and buildings and reasonable accommodation will be provided for participants and staff with individual needs.

Democracy

[14] Statistical yearbook 2022. Department of Economic and Social Affairs Statistics Division. UN 2022.

The action does not tackle democratic processes. However, it will contribute to people being healthy and employed in the life science industry, and therefore able to participate in the democratic life. It will particularly benefit the youth.

Inequality Reduction

As per the Inequality Marker, the Action is labelled as I-1. The objective of this Action is increasing equitable access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all Africans. This objective pursues SDG 3.8 and 10 and promotes ultimately universal health coverage (UHC), contributing to inequality reduction. Strengthening pharmaceutical production in some African countries is a step towards making global supply chains more resilient and will be valuable in reducing inequalities by ensuring that production also benefits non-producing African countries, with funding flows that support the continental market while ensuring equitable access for all, including the poorest. Activities under Outcome 2 will also help better identify heath inequality drivers by closing the data gaps.

Conflict sensitivity, peace and resilience

The action will promote health systems resilience, pandemic preparedness and global health security. Populations in territories with unresolved and/or ongoing conflicts, asylum seekers and refugees are disproportionately affected by the recent health crisis due to restrictions in movements, limited humanitarian aid and limited access to and lack of proper health products.

Disaster Risk Reduction

COVID-19 pandemic has generated damage to societies and economies globally and has highlighted the need for robust health system and increased quality pharmaceutical production worldwide. Enabling an adequate environment for local production is a prerequisite for allowing access to quality, safe and effective health products to the population. This measure will contribute to improve health outcomes, to enhance response capacity and diminish the risk posed by the many epidemics and diseases that recurrently affect the African continent, as well as economic growth.

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	Numerous initiatives focusing on vaccine production leading to overlaps, duplication of efforts and	**Medium**	**Medium**	The proposal will ensure adequate project preparation, due diligence and support to sustainable projects, and frequent dialogue with African and international actors.

	inefficiencies in the support provided. Projected manufacturing capacity may be higher than needs.			
	Potential difficulties to engage diverse financing institutions in a collaborative way to invest in infrastructures and other key areas.	**Medium**	**High**	The governance (organisational set up) of the platform should allow for active participation from the EC and all concerned banks to review the pipeline of project once the lead implementer is selected. Likewise, specific reporting tools should be in place, particularly linked to the MAV+ results framework.
	Locally-produced vaccines, medicines and other health products are not purchased by African governments for budget, cost, regulatory or other reasons; and continue to rely on imports.	**Medium**	**High**	Continue to support the AU and WHO work to strengthen the regulatory maturity level of National Regulatory Authorities and involve all stakeholders in the development of innovative solutions for local production and, importantly, to incentivise a predictable demand and pooled procurement. Involvement of global health initiatives (e.g. Global Fund, Gavi) in order to gain their political and operational support. Research and innovation will ensure products diversification and production of health products adapted to the diseases encountered locally, what will mitigate the risks of products that cannot be used.
Planning, processes and systems	High level of complexity, with an array of different stakeholders. In a micro level, a main risk is associated with the relatively short timeline for concluding the contract and the additional TAM/African Operational Board Procedure.	**High**	**High**	The overarching strategy for the TEI will focus on the key levers that can be used to affect change, will empower African ownership and institutional development, will identify EU's 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. Regarding timing, while short it shall be sufficient given that some projects have been pre-identified.
Planning, processes and systems	Low national resources (financial, infrastructure, human) made available by governments to guarantee the success of the local manufacturing agenda.	**High**	**High**	Use this action to pool resources (financial and technical), advance coordination in a Team Europe approach, and advocate for countries to invest pharma systems, including public procurement of locally produced goods.

People and the organisation	Future reduction in the current level of political interest in this agenda, or staff turnover, could hamper the strategy and the coordination across the TEI in the longer term.	**Medium**	**High**	Momentum and enthusiasm amongst partners in the Team Europe Initiative will be built and harnessed through 1) the High Level Steering Committee (EU-AU), 2) the EU Member States Task Force (monthly meetings coordinated by the EC), and 3) the Team Europe Support Structure (TESS) implemented by Enabel, GIZ and Expertise France. The MAV+ strategy will be monitored on the basis of our full range of capabilities, whilst ensuring that different components can deliver impact. Close alignment with PAVM's priorities will also ensure co-creation with African partners.
Communication and information	Potential use of communication methods misaligned with the Commission's strategy, and inadequate eus of EU's visual identity. Risk of low EU visibility inherent in acting through implementing partners. Misalignment in terms of general culture and position of these countries when coming to governance issues in public health affect the outcome of the specific initiative, but also the ability to cooperate and trust the countries in question.	**Medium**	**Low**	It will be mitigated by actively connecting communications teams in the Commission with the communication teams of implementing partners (DFIs). Effort will be done and consideration given to understanding general culture and position of these countries when coming to governance issues in public health.
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**	EU to support the upgrade when necessary of national pharmaceutical strategies. Continental and regional organisations and governments in Africa should be developing legal framework promoting transparency, responsible sale and rational use, and also protecting the sector against falsified medicines and vaccines with enforceable legal provisions. Legal framework has to be developed further according with experiences from AU and EU MS, WHO, UNICEF, UNFPA and in

				line with the UN Guiding Principles on Business and Human Rights.
Planning, processes and systems	Several organisations, MS and EC Services are working in research and innovation, there is a risk of overlap	**Medium**	**Medium**	Commission services are consulted, and the activities will be developed in co-creation, in order to ensure complementarity and, whenever possible, synergies on innovation and STI aspects.

Lessons Learnt:

Producing vaccines is a complicated process with different technologies potentially involved (from viral vector to mRNA). The production process consists of three phases: 1. Producing the raw version of the vaccine (upstream); 2. Producing the specific version of the vaccines (downstream); 3. Filling ampoules and packaging for distribution (fill-and-finish). The processes differ for different kinds of vaccines. In all cases, the process is complicated and entails working with biological and therefore unpredictable materials. The production of highly qualified vaccines has several challenges: highly qualified personnel and specialised equipment, adequate control mechanisms and consistency of the production process, technology transfer between partners, global supply chains and an enormous international network, timely availability and longterm production process, large amount of components needed.

Producing vaccines requires effective global supply chains. Supply chains must be connected seamlessly to deliver the products in time, especially under pressure of a pandemic. By illustration: a pharmaceutical company explained that for the production of the COVID-19 vaccines, 280 components, coming from 86 locations in 19 countries, are needed, demonstrating the high complexity of the process. A complicating factor for the development and production of vaccines and medicines in times of a pandemic, as seen during COVID-19, is that the focus on the production of one particular product (i.e. against the new virus), increases the pressure on the supply chain for producing other health products, including treatments against cancer or immune diseases and family planning.

In the case of medicines, including generics, there are other challenges, including sourcing the active pharmaceutical ingredients (APIs) and obtaining a competitive price.

The main lesson learnt from the production and value chain perspective is the need to forge multi-actor partnerships and, notably, the importance of adequately partner with governments, financing institutions and pooling technical expertise, which is scarse.

General EC / EU 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 MAV+, being more targeted than previous ones. MAV+ also looks at the specific value of the EU as a regional entity itself and in comparison to other donors active in this space, 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 (UHC) 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 recently provided financial support to the WHO *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.* EU contribution focused 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.

In 2003 the European Union, together with European and African countries, committed to support the conduct of clinical trials to accelerate the development of medical interventions fighting poverty related infectious diseases particularly affecting sub-Saharan Africa: the European and Developing Countries Clinical Trials Partnership (EDCTP). It has provided support to collaborative clinical trials and clinical studies, strengthen the enabling environment for conducting clinical trials and clinical research by supporting ethics and regulatory capacities and support fellowships that focus on career development of African researchers. EDCTP is one of the founder members of the African Vaccine Regulatory Forum (AVAREF) one of the technical committees under AMRH. EDCTP 3 is now, in the new form of joint undertaking, joining forces with the private sector.

The European Medicines Agency (EMA), in cooperation with the World Health Organisation (WHO), can provide scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union (EU). The procedure is called EU-Medicines for all or 'EU-M4all'. The experience of EMA through this procedure as well as its experience in supporting the WHO Prequalification programme (for inspections and assessments) can help AMA to define a framework for collaboration with all African authorities as well as with international partners such as EMA or the WHO Prequalification programme. A new contract with EMA to work with African regulators is expected to be signed in 2023.

This action will also seek synergies with ongoing country level actions, ongoing regional actions (PAVM, AMRH, AMA, SIPS -Support to Industrialisation and the Productive Sector-, Medisafe), and with EU-funded global health initiatives such as COVAX, Gavi, and The Global Fund.

African initiatives (PMPA, AMRH, PAVM, 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 by enough countries to be established. Further strengthening and harmonisation of regulatory systems will be essential. 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 authorities (NRAs), regional economic communities (RECs), AUC, Pan African Parliament (PAP), the World Health Organisation (WHO), the Bill & Melinda Gates Foundation (BMGF), the Foreign, Commonwealth & Development Office (FCDO, UK), 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 authorisation 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. 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, demonstrating that there are other issues beyond regulatory harmonisation that need to be addressed to support development of the sector.

The COVID-19 Vaccine Development and Access Strategy endorsed by the AU in August 2020 provided a framework to guide partners' efforts in support of Africa's needs in that context. Later on, in April 2021, the African Union and Africa CDC launched the Partnerships for African Vaccine Manufacturing (PAVM). In July the same 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 immunisation vaccines will be produced locally and sustainably by 2040.

3.5 The Intervention Logic

The underlying intervention logic for this action is the following:

1. **Enhanced financial inclusion of African operators along the pharmaceutical value chain, innovators and manufacturers of essential vaccines, medicines or health technologies that supply African markets and local health systems.**

Outcome 1 is key to ensure that essential vaccines, medicines and health technologies reach African markets and are available in local health systems. The *conditio sine que non* to succeed in diversifying global value chains and be able to manufacture health products in *Africa for Africa* is making catalytic financing available for project preparation, obtaining market intelligence, de-risking loans and making them more affordable. This component proposes the creation of a Thematically Focused Project under the African Investment Platform that will make available non-refundable resources to incentivise sustainable production and acquisition of vaccines, medicines and health technologies in Africa by filling the gaps not satisfied through other potentially available resources such as EU guarantees and bank's own resources. The advantages of a regional solution are: 1) having one assistance mechanism that pools expertise for various countries, 2) having a portfolio approach to spread the risk, and 3) allowing a regional value chain approach.
There are several ways in which the EU as a lead donor in the sector can help develop sustainable, innovative production sites and networks while seeking social returns to the investments. Considering market failures, public (donor) intervention is justified to ensure access to sustainable finance and product diversification according to the health needs of the population. EU grants can be transformed into catalytic financing (for technical project assistance, CapEx, OpEx or premiums) complementing other EU financing instruments such as guarantees. The matrix would be coupled with equity or concessional loans provided by financing institutions as own resources, and with own resources from partner governments.

The allocation can be used for pooled technical assistance for project preparation, hence to advance the vision of the access to finance pillar of the AU's PAVM, which is co-led by the African Development Bank and Afreximbank in collaboration with European DFIs and IFC. Revolving grants for example for SMEs, innovators and new entrants in case they obtain benefits, and de-risking tools, i.e. export credit guarantees, could be considered. It will also be critical to analyse markets and identify the essential supplies or molecules whose production is still limited or insufficient. The allocation will allow to implement the projects in the pipeline (to be mature second half of 2024) by offering grants for capital or operational expenditures, or a resilience premium to select new manufacturers, depending on the concrete needs.

The focus will be local production, yet R&D actions leading to local production to meet public health needs, procurement or locally produced goods, and activities througout the whole value chain until patients are reached could be supported.

Therefore, the project will allow to overcome market failures through blended finance (combining primarily technical assistance with investment grants). The final element to succeed in pharmaceutical manufacturing agenda is making demand more predictable. The demand side can be reinforced through 'pull' incentives (e.g. through volume guarantees or advanced purchase agreements). In this sense, there are programmes (propoposed investment programmes, PIPs) under the EFSD+ Open Architecture that could offer bridge financing or volume guarantees complementing the 'push' incentives created by the project described in this note. These PIPs have been submitted by EIB/Gates (Human Development Accelerator) and EDFI (Transforming Global Value Chains). A third PIP also refers to MAV+ (First Movers Health Investors Fund by FMO/Cardano). It is not possible to anticipate at this stage the concrete use of guarantee resources, yet they must be complemented with grants and loans in order to have an adequate financing matrix. In other words, guarantees alone are insufficient to overcome existing challenges. The EC will ensure as much as possible alignment and reinforcement between the various instruments when they target common objectives from different angles.

By no means this vehicle will offer a privileged position to one single financial institution or a single company. There are other examples in the EU like InvestEU or InnovFin – EU Finance for Innovators. Several financing institutions have confirmed their interest in this proposal, having a pipeline of projects that could be implemented starting in the second half of 2024. Countries to host these projects include tentatively Rwanda, Ghana, Senegal, South Africa, Nigeria, Kenya (non-exclusive list).

2. Improved ecosystem for <u>private sector's full engagement</u> in the development and manufacturing of essential vaccines, medicines and health technologies in Africa.

This component will contribute to identify promising new health solutions in the health products and technologies domain, and make them accessible, available and affordable for the African population. The objective is incentivising such solutions by improving the ecosystem, not only through a mere regulatory perspective (covered through ongoing actions) but rather by advancing other usually ignored fronts like the predictability and completeness of health laws, adequate pricing and reimbursement policies, or ensuring transparency in R&D costs.

The private sector is an important leading actor in increasing the production of vaccines, medicines and medical technologies given its capacity to innovate, to quickly adapt to changing needs and circumstances and to scale up successful solutions. Opportunities are discerned in the fields of digitalisation (e-health, e-pharma), innovative financing, logistics and sharing biomedical and technological knowhow. Key to formulating an effective response is to match demand for health solutions with the availability of innovative solutions. To effectively engage the private sector, a diversified approach is needed that takes into account the contextual differences and focus areas.

3.6 Logical Framework Matrix

This indicative logframe 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 2023**	**Targets 2028**	**Sources of data**	**Assumptions**
Impact	To increase equitable access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all in Africa, 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 project once operative	10 points increase from baseline value (depending on product) in selected countries	1.WHO/HAI methodology to generate reliable information of the price, availability, and affordability of selected essential medicines 2.World Bank databank. 3. Project itself.	*Not applicable*
Outcome 1	1. Enhanced financial inclusion of African operators along the pharmaceutical value chain, innovators and manufacturers of essential vaccines, medicines or health technologies that supply African markets and local health systems.	1.1. Number of quality assured vaccines / medicines / health technologies or products locally produced with support from the Action. - dissagregated by health application, age group targeted, gender targeted, disability targeted, income and place of residence.	1.1.0 1.2. 0 1.3. TBC 1.4. 1	1.1. 500 million doses. 1.2. 5 companies.	Internal monitoring systems of the TEI. Implementers, companies supported, and publicly available data (e.g. AU, Ministries of Health).	A steering / governance mechanism exists for collaboration with DFIs

		1.2. Number of supported SMEs that report an improvement in their market linkages, disaggregated by sex and age (15-30 years) of leader, area/sector where relevant (EFSD+, MSMEs, Ind. 26) 1.3 Total volume of investments of African operators to produce essential vaccines, medicines or health technologies for the African markets and local health systems. 1.4. Number of African operators, innovators and manufacturers of essential health products that supply African markets and local health systems with new or improved products thanks to enhanced access to financial services.		1.3. 500 million (x10) 1.4. 4		
Outcome 2	2. Improved ecosystem for private sector's full engagement in the development and manufacturing of essential vaccines, medicines and health technologies in Africa.	2.1 Number of medicines legal frameworks revised. 2.2. Number of relevant internal policies and practices applied by companies favouring equitable access disaggregated by policies that include gender equality objectives, in line with GAP III (EFSD+, cross sector, Ind. 24)	2.1. 0 2.2. 0	2.1 5 2.2 3	2.1. Implementers, based on reported information. 2.2. Implementers, based on publicly available information.	
Output 1 related to Outcome 1	1.1. Increased catalytic/de-risking funding opportunities to pharmaceutical companies, particularly local and SMEs, alone or in partnership with the public sector, linked to the production of treatments for infectious diseases of high	1.1.1. Number of loans served among relevant target group, disaggregated by target group, by sex and age (15-30 years), by type of intermediary, by type of product,	1.1.1 - 0 1.1.2 0	1.1.1 Minimum 4-5 1.1.2. 100 million	Internal monitoring system.	

	prevalence in Africa as well as neglected tropical diseases.	by served area/sector where relevant (EFSD+, MSMEs, Ind. 5) 1.1.2. Additional capital unlocked through the set-up of de-risking mechanisms and other confidence tools to attract investors (specify if relates to sustainability-related instruments or products) (EFSD+, cross sector, Ind. 9) 1.1.3. Ratio between the total investment (from IFI, public and private investors) against the EU coverage (EFSD+, cross sector, Ind. 4 measuring multiplier effect) 1.1.4. 1.4. Number of beneficiaries with access to financial services with TEI support: (a) firms, (EFSD+ MSMEs, Ind. 8, GERF) 1.1.5 Ratio between the amount of reimbursable finance (by IFIs or other financiers) against EU contribution (EFSD+, cross sector, Ind. 10) 1.1.6. Number of quality assured vaccines / medicines / health technologies procured for distribution in Africa. - dissagregated by health application, age group targeted, gender targeted, disability targeted, income and place of residence.				
Output 2 related to Outcome 1	1.2 Improved dissemination of evidence and knowledge about		1.2.1. 0	1.2.1. 100	Internal monitoring system.	

	african countries's public health needs in the context of MAV+	1.2.1. Number of policy makers, public health practitioners, investors, health care providers who participate in events organised with TEI support to identify, analyse and share emerging health needs in African countries and regions, disaggregated by type, gender and country of residence.				
Output 3 related to Outcome 1	1.3. Expanded pipeline of relevant, viable and bankable projects in alignment with the PAVM's vision and MAV+ access to finance work stream	1.3.1. Number of companies supported with a business plan / project preparation. 1.3.2. Number of projects developed that meet the requirements of PAVM's vision and MAV+ access to finance work stream. 1.3.3. Number of studies supported (technical, economic, and environmental, gender) (EFSD+, MSMEs, Ind. 34)	1.3.1 0 1.3.2 0 1.3.3 0	1.3.1. 5 1.3.2 5 1.3.3 1		
Output 4 related to Outcome 1	1.4. Increased availability of market intelligence and business opportunities for the pharma and biotech industries in Africa.	1.4.1. Number of pharma and biotech industries in Africa which benefitted from market intelligence supplied with the support of the TEI, disaggregated by country.	1.4.1 0	1.4.1. 5		
Output 5 related to Outcome 1	1.5. Increased resilience of manufacturing facilities and health commodities in the continent	1.5.1. Number of facilities improved or constructed with the TEI support (by type, by country), which will be able to produce COVID-19 vaccines or other outbreak vaccines.	1.5.1 0	1.5.1 4		

Output 6 related to Outcome 1	1.6. Increased availability of health products locally and sustainably produced.	1.6.1. Number of quality assured vaccines / medicines / health technologies procured for distribution in Africa, disaggregated by health application, age group targeted, gender targeted.	1.6.1 0	1.6.1 500 million		
Output 1 related to Outcome 2	2.1. Increased development of tested and affordable new health solutions in the health products and technologies domain for the African population.	2.1.1. Number of new solutions developed and tested with TEI support with potential to be scaled up	2.1.1 0	2.1.1 2		
Output 2 related to Outcome 2	2.2. Increased understanding of local legal requirements to operate including for market authorisation, WHO prequalification, technology transfer, distribution, rational use, management of intellectual property or good manufacturing practices (GMPs).	2.2.1. Number of initiatives supported (of which number of those that include dialogue on gender equality) (EFSD+, MSMEs, Ind. 33)	2.2.1 0	2.2.1 6		
Output 3 related to Outcome 2	2.3. Improved knowledge sharing on adequate pricing policies, particularly those directly and voluntarily applied by companies.	2.3.1. Number of professionals/staff trained or coached disaggregated by sex and age and by type of organisation (EFSD+, MSMEs, Ind. 37)	2.3.1 0	2.3.1 50		
Output 4 related to Outcome 2	2.4. Improved knowledge sharing on effective reimbursement policies by governments.	2.4.1. Number of staff trained.	2.4.1 0	2.4.1 50		
Output 5 related to Outcome 2	2.5. Improved mechanisms and tools for transparency in R&D costs and cost components, notably for those companies obtaining public EU benefits.	2.5.1 Number of companies disclosing their cost components.	2.5.1 0	2.5.1 4		
Output 6 related to Outcome 2	2.6. Higher market intelligence and data on market actors and market failures, and better understanding of inequality drivers (i.e. across population groups and countries).	2.6.1. Number of studies produced.	2.6.1 0	2.6.1 4		

Output 7 related to Outcome 2	2.7 Stengthened public-private dialogue, engagement and collaboration.	2.7.1. Number of countries in dialogue with EUDs and European private sector	2.7.1 4	2.7.1 5		

4 IMPLEMENTATION ARRANGEMENTS

4.1 Financing Agreement

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

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 60 months from the date of adoption by the Commission of this Financing Decision.

Extensions of the implementation period may be agreed by the Commission's responsible authorising officer by amending this Financing Decision and the relevant contracts and agreements.

4.3 Implementation 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[15].

4.3.1 Contribution to the African Investment Platform

This contribution may be implemented under indirect management with the entities, called Lead Finance Institutions, identified in the appendix to this Action Document. The implementation entails

Regarding the selection of individual projects, preferably under a single application, specific requirements will be applied. The implementation entails:

- The existence of strong public health interest (based on products/antigens targeted, scientific, medical and geographical interest, etc.)
- The sustainability of the proposal (solid concept and business plan, appropriate human and technical capacities, socio-economic impact),
- As well as equity, quality, and willingness to adopt transparency and fair pricing parameters.

Lead Finance Institutions will be selected using the following criteria: :

- An ability to collaborate with partner countries, private sector clients, and other financing institutions.
- Human and financial capacity (i.e. the potential to invest additional own resources).
- Alignment with partners following a Team Europe approach and Global Gateway concepts.
- Experienced capacity in risk management.
- Long-term engagement.
- Ability to analyse and adequately respond to a variety of stakeholder requests, including from individual companies and innovators and multi-stakeholder projects.
- Ability to manage a platform that will promote the African local research, innovation and production of health products, the collaboration with the EU, and that will ensure full respect for human rights and equal treatment of all.
- The coherent articulation of the proposed processes with related work streams in the overall TEI, MAV+, and the PAVM.

[15] 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.

A list of Financial Institutions is provided in the Appendix.

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

In case the preferred implementation modality under indirect management foreseen in Section 4.3.1. cannot be implemented due to unforeseen circumstances outside the Commission's control, Specific Objectives 1 and 2 outlined in section 2.1 might be implemented in direct management through grants.

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 carrying out of this action impossible or exceedingly difficult (Article 28(10) NDICI-Global Europe Regulation).

For this multi-country action, natural persons who are nationals of, and legal persons who are effectively established in the following countries and territories covered by this action, are also eligible: all countries in Sub-Saharan Africa.

4.5 Indicative Budget

Indicative Budget components	**EU contribution (amount in EUR)**	**Third-party contribution, in currency identified**
Implementation modalities – cf. section 4.3.1.		
Objective/Outputs 1 –Enhanced financial inclusion of African operators along the pharmaceutical value chain, innovators and manufacturers of essential vaccines, medicines or health technologies that supply African markets and local health systems.		
Contribution to the African Investment Platform	45 000 000	5 000 000
Objective/Output 2 - Improved ecosystem for private sector's full engagement in the development and manufacturing of essential vaccines, medicines and health technologies in Africa.		N.A.
Contribution to the African Investment Platform	5 000 000	5 000 000
Evaluation – cf. section 5.2 **Audit** – cf. section 5.3	May be covered by another Decision	N.A.
Contingencies	N.A.	N.A.
Totals	50 000 000	10 000 000

4.6 Organisational Set-up and Responsibilities

Specific project set-up (MAV+ III)

The project governance structure will consist of a steering committee, a secretariat, and country level implementation units. The steering committee will provide strategic steering and oversight and take high level decisions on country and thematic components. It will consist of representatives of the Lead Financing Institution(s), the European Commission (Headquarters, EU Delegations and other specialists within the Commission services, as appropriate) and potentially others if deemed appropriate.

As the engagement of public sector stakeholders (central governments and other administrative bodies) is a key enabling factor, the partnership between the EC, the EU Delegations and the Financing Institution(s) in the target countries aims at fostering a conducive investment environment through the creation of an articulated policy dialogue and a sense of ownership by these local players. It will be important to actively engage with the AU and notably the PAVM initiative, and with Ministries of Health and other related Ministries (finance, economy, trade).

The project intends to be a collaborative scheme by which regardless of having a Lead DFI, several DFIs can contribute and benefit. Other key international partners may also be consulted as appropriate (WHO, global health initiatives, etc.).

General MAV+ steering

This action contributes to the access to finance, access to markets and private sector work streams under MAV+.

Given the complexity and dynamics of MAV+, that has the ambition to address multiple dimensions at the intersection of health, industry, trade, research and education, a governance structure with 2 levels, policy and operational, and 3 layers, is being put in place for coordinating the variety of continental and country actors and actions. The model is under finalisation and in principle comprises:

1. A High-Level Steering Committee (HLSC) to provide policy and overall strategic guidance of the programme. It reflects the high-level political dimension and the regional and continental impact of this flagship initiative, as well as the specific modalities of implementation. Meetings (2/year) will be co-chaired by the EC INTPA (Deputy Director in charge of Health) and AUC representative. The members are representatives of AU MS and African key organisations (e.g. Africa CDC) and TE (EU MS and European DFIs).

2. At operational level:

a) A Management Team (MT) to provide operational guidance, define milestones and coordinate the TE members, including EC internal coordination and TE coordination with the key African and International organisations.

The members of the Management Team are Commission services (the Flagship project team including thematic, horizontal and geographical Units), the EU MS and the European financial institutions (the MS Task Force). The MT coordinates the dialogue with the African regional and continental organisations involved in the Partnerships for African Vaccines Manufacturing (PAVM) hosted by the Africa Centres of Diseases Control and Prevention (ACDC), with the private sector and with the international organisations. The MT will continue to close collaborating with the PAVM that has been empowered to driving the African continental strategy of vaccine manufacturing, and, in order to do that, of coordinating and aligning with non-African partners. (All the MS and European financial institutions are welcome to be members).

b) A MAV+ Team Europe Support Structure (TESS) to offer the technical services needed both for supporting the MT and for the work streams coordinated implementation, monitoring and reporting. This mechanism aims at ensuring the coherent articulation of all MAV+ components and work streams in the overall TEI, and will mobilise technical and managerial expertise for capacity development and key complementary activities (e.g. knowledge management, theory of change and programme monitoring, financial reporting, etc.). Likewise, it will also underpin the PAVM. The secretariat is based on a multi-actor partnership agreement of the

EC with a consortia of MS' implementing partners (agencies) and is led by Enagel together with GIZ and Expertise France.

5 PERFORMANCE MEASUREMENT

5.1 Monitoring and Reporting

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

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

Roles and responsibilities for data collection, analysis and monitoring: the implementing partners is in charge of data collection and reporting, and to that end can allocate a reasonable part of the budget to this end. Surveys and studies can be financed under the regular budget of the action, through specific budget lines.

Monitoring systems for MAV+ related actions are foreseen. While all individual actions under MAV+ will be subject to monitoring and reporting through their respective implementers, an external evaluation could be envisioned, covering MAV+ alone or together with other health related TEIs.

All monitoring and reporting shall assess how the Action is considering the principle of inequality including gender equality, human rights-based approach, and rights of persons with disabilities including inclusion and diversity indicators shall be disaggregated at least by sex, and if possible, by age, income and place of residence. The Action will monitor and report on the gender equality results achieved by the project in the evaluation phase.

5.2 Evaluation

Having regard to the nature of the action, a mid-term and a final external evaluation may 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 evaluation will assess to what extend the Action is taking into account the human rights-based approach and how it contributes to inequality, including gender equality and women's empowerment. Expertise on human rights and gender equality will be ensured in the evaluation teams.

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 may be shared with partner countries and other key stakeholders following the best practice of evaluation dissemination. The Commission shall analyse the conclusions and recommendations of the evaluations and, where appropriate, apply the necessary adjustments.

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

5.3 Audit and Verifications

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

6 STRATEGIC COMMUNICATION AND PUBLIC DIPLOMACY

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

In line with the 2022 'Communicating and Raising EU Visibility: Guidance for External Actions', 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 in principle no longer required to include a provision for communication and visibility actions promoting the programmes concerned. These resources will instead be consolidated in Cooperation Facilities established by support measure action documents, allowing Delegations to plan and execute multiannual strategic communication and public diplomacy actions with sufficient critical mass to be effective on a national scale.

Appendix 1 REPORTING IN OPSYS

A Primary Intervention (project/programme) is a coherent set of activities and results structured in a logical framework aiming at delivering development change or progress. Identifying the level of the primary intervention will allow for:

Articulating Actions or Contracts according to an expected chain of results and therefore allowing them to ensure efficient monitoring and reporting of performance;

Differentiating these Actions or Contracts from those that do not produce direct reportable development results, defined as support entities (i.e. audits, evaluations);

Having a complete and exhaustive mapping of all results-bearing Actions and Contracts.

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 chosen can be modified (directly in OPSYS) and the modification does not constitute an amendment of the action document.

The intervention level for the present Action identifies as (tick one of the 4 following options);

Action level (i.e. Budget Support, blending)		
☐	Single action	Present action: all contracts in the present action
Group of actions level (i.e. top-up cases, different phases of a single programme)		
☒	Group of actions	Actions reference (CRIS#/OPSYS#): Present action: ACT-62011 (MAV+ III) Other actions: ACT-61342 (MAV+ II) ACT- ACT-61139 (MAV+ I)
Contract level		
☐	Single Contract 1	Contribution agreement
	(…)	
Group of contracts level (i.e. series of programme estimates, cases in which an Action includes for example four contracts and two of them, a technical assistance contract and a contribution agreement, aim at the same objectives and complement each other)		
☐	Group of contracts 1	<foreseen individual legal commitment (or contract) 1> <foreseen individual legal commitment (or contract) 2> <foreseen individual legal commitment (or contract) #>

APPENDICE 2 LISTE DES INSTITUTIONS FINANCIERES CHEFS DE FILE ELIGIBLES

Acronyme de l'Entite Juridique	**Entite Juridique**
MULTILATERAL FINANCIAL INSTITUTIONS	
EIB	European Investment Bank
EBRD	European Bank for Reconstruction and Development
WBG	World Bank - International Finance Corporation
EU BILATERAL FINANCIAL INSTITUTIONS	
KfW	Kreditanstalt fur Wiederaufbau
AFD	Agence Frarn;:aise de Developpement
AECID	Agencia Espanola de Cooperaci6n Internacional para el Desarrollo
CDP	Cassa di Depositi e Prestiti
COFIDES	Compafiia Espanola de Financiaci6n de! Desarrollo
FMO	Entrepreneurial Development Bank
RVO	Rijksdienst voor Ondernemend Nederland (Netherlands Enterprise Agency)
BIO	Belgian Investment Company for Developing Countries
EDFI	European Development Finance Institutions
REGIONAL DEVELOPMENT FINANCE INSTITUTIONS	
ADB	Asian Development Bank
AIDB	African Development Bank
IDB	Inter-American Development Bank
BCEAO	Central Bank of West African States
WADB	West African Development Bank
DBSA	Development Bank of Southern Africa
EADB	East African Development Bank
TDB	The Eastern and Southern African Trade and Development Bank
CABEI	The Central American Bank for Economic Integration
CAF	Development Bank of Latin America
CDB	The Caribbean Development Bank