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ANNEX

to the Commission Implementing Decision on the financing of a special measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies in Africa for 2023

Action Document pertaining to the Special Measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies in Africa for 2023

SPECIAL MEASURE
This document constitutes the *annual* work programme within the meaning of Article 110(2) of the Financial Regulation.

1 SYNOPSIS

1.1 Action Summary Table

1. Title **CRIS/OPSYS reference** **Basic Act**	OPSYS numbers: ACT-62262 (Senegal) ACT-62266 (Egypt) ACT-62268 (South Africa) ACT-62269 (Rwanda) ACT-62270 (Ghana) ACT-62271 (Nigeria) Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe)
2. Team Europe Initiative	Yes Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (TEI MAV+) for Sub-Saharan Africa, expanded to North Africa
3. Zone benefiting from the action	The action shall be carried out in Senegal, Rwanda, Ghana, South Africa, Nigeria, Egypt.
4. Programming document	NA
5. Link with relevant MIP(s) objectives / expected results	This Action will complement TEI MAV+ activities funded through the regional Sub-Saharan Africa Multi-Annual Indicative Programme (RIP SSA), and will support objectives related to health in the respective benefiting SSA and North-Africa countries' MIPs: Egypt: Specific Objective 3.3. "To contribute to decent and healthy lives, through

	access to basic services and social inclusion“. Senegal: Specific Objective 2.3.: "Improve access, particularly for the most vulnerable, to basic healthcare and health services and promote the emergence of pharmaceutical sovereignty.” Rwanda: Specific Objective 1.1 “Support access to and quality of TVET” and Specific Objective 3.3 “Strengthened economic governance” Ghana: Specific Objective 3 “Improve efficiency, relevance and quality of TVET and higher education to boost employment in the green, digital and pharmaceutical sectors". South Africa: Specific Objective 1 of priority area “Partnerships”, “to foster policy and capacity development, notably through knowledge exchange and technologies". Nigeria: Specific Objective 3.3: “To contribute to decent and healthy lives including through access to safe, effective, quality and affordable essential vaccines, medicines and health technologies“.
PRIORITY AREAS AND SECTOR INFORMATION	
6. Priority Area(s), sectors	The proposed Action will contribute to Priority area 1 of the RIP SSA – Human Development and aims to achieve Specific Objective 1: Strengthen the African health security architecture, pharmaceutical systems and public health capacity, contributing to stronger health systems and improved health, including sexual and reproductive health rights (SRHR) outcomes. The Action will partly contribute also to Specific Objective 2 on quality education and skills development. As support to strengthening IT systems that is critical for the sector is also envisaged, the action will potentially contribute to Priority area 4 - Digital and Science, Technology and Innovation as well.
7. Sustainable Development Goals (SDGs) [1]	Main SDG (1 only): SDG 3 (Ensure healthy lives and promote well-being for all) Other significant SDGs (up to 9) and where appropriate, targets: SDG 4 (Quality Education and Lifelong Learning for all), SDG 5 (Gender Equality), SDG 8 (Decent Work and Economic growth), SDG 9 (Industry and innovation), and SDG 17 (Partnership)
8 a) DAC code(s) [2]	Development Assistance Committee (DAC) code 12110, Health policy and administrative management – 65% DAC code 32168, Pharmaceutical production – 20% DAC code 11430 Advanced technical and managerial training –15%
8 b) Main Delivery Channel [3]	EU Member States development agencies - Other public entities in donor country 11004

[1] Relevant SDGs can be identified with the *SDG Mapper*, an electronic support tool for intervention managers.
[2] DAC sectors (codes and descriptions) are indicated in the second and fourth columns of the tab ‘purpose codes’ in the following document: https://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/dacandcrscodelists.htm (Make sure to not enter voluntary codes from the third column as these are not available in OPSYS)
[3] Channels are indicated in the second and fifth columns of the tab ‘Channel codes’ in the following document: https://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/dacandcrscodelists.htm. Please do not use codes 10000, 90000, [others]… not available in OPSYS.

9. Targets[4]	☐ Migration ☐ Climate ☒ Social inclusion and Human Development ☒ Gender ☒ Trade and Investment ☐ Biodiversity ☒ Education[5] ☐ Human Rights, Democracy and Governance[6]			
10. Markers [7] **(from DAC form)**	**General policy objective** @	**Not targeted**	**Significant objective**	**Principal objective**
	Participation development/good governance	☐	☒	☐
	Trade/investment/customs facilitations/IPR	☐	☒	☐
	Aid to environment @	☒	☐	☐
	Gender equality and women's and girl's empowerment	☐	☒	☐
	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 @	☒	☐	☐

[4] Actual contribution to targets will be confirmed ex-post based on a standardised methodology.
[5] This target is specific to INTPA. If the action is marked as contributing to the Education target, please make sure the target on "Social inclusion and Human Development" is also marked.
[6] Thematic target for geographic programmes (at least 15%) in delegated act.
[7] For guidance, see https://www.oecd.org/development/financing-sustainable-development/development-finance-standards/ (go to "Data collection and resources for reporters", select Addendum 2, annexes 18 (policy) and 19 (Rio) of the reporting directive).
If an action is marked in the DAC form as contributing to one of the general policy objectives or to RIO principles as a principal objective or a significant objective, then this should be reflected in the logframe matrix (in the results chain and/or indicators).

	Combat desertification @	☒	☐	☐
	Climate change mitigation @	☒	☐	☐
	Climate change adaptation @	☒	☐	☐
11. Internal markers[8] and Tags[9]:	**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 @[10]	☒	☐	☐
	Reduction of Inequalities @	☒	☐	☐
	Covid-19	☐	☒	☐
BUDGET INFORMATION				

[8] The internal markers have been created to report on the implementation of the Commission's own policy priorities in areas where no DAC reporting tool is available. For the sake of consistency and comparability, the methodology is equivalent to the DAC markers, with three possible positions (main target, significant target, not targeted)

[9] Methodology for additional tagging providing granularity on internal markers is under development. When a marker is Significant or Principal Objective, please also choose the relevant yes/no tag.

[10] Guidance note available in ARES.

12. Amounts concerned[11]	Budget line(s) (article, item): (Ghana, Nigeria and Senegal, 14.020120): EUR 75 000 000 (Rwanda, 14.020121): EUR 40 000 000 (South Africa, 14.020122): 16 000 000 (Egypt, 14.020110): 3 000 000 Total estimated cost for 2023: EUR 134 000 000 Total amount of EU budget contribution for 2023: EUR 134 000 000
MANAGEMENT AND IMPLEMENTATION	
13. Type of financing[12]	**Indirect management through** pillar assessed entities **Indirect management** with the Lead Financial Institutions **Direct management** through grants and procurement

1.2 Summary of the Action

This special measure seeks to advance country level actions in Sub-Saharan Africa (SSA) and Southern Neighbourhood aiming to enhance manufacturing capacities and access to quality, safe, effective and affordable vaccines, medicines and health technologies in Africa, in line with the objectives of the Team Europe initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (TEI MAV+), and that are deemed critical for sustainability and impact. They will complement, benefit from and reinforce the TEI MAV+ regional actions funded under the RIP for SSA. The objectives pursued by the annual measure to be financed under 'Sub-Saharan Africa' and 'Neighbourhood' geographic programmes of the Regulation (EU) 2021/947 should support the advancement of country level interventions in Africa deemed critical for reinforcing local manufacturing capacities and creating an improved access to health products in Africa and contribute to the implementation of the Global Gateway strategy[13] and the EU Global Health Strategy[14].

Main outputs revolve around the following priorities:

1. Skills development through higher education and vocational training (TVET), considering gender and disabilities inclusion approach, within the context of biomanufacturing and the pharmaceutical industry.
2. Private sector, with a focus on, sustainability, local ecosystems, entrepreneurs and SMEs.
3. Quality assurance along the national supply chains.
4. Research and development (R&D) associated to new or improved health products.
5. Technology transfer focusing on local organisations and in view of shared African and European interests.
6. Regulatory strengthening at country level in coordination with regional level actions that are being implemented under the RIP SSA with the European Medicines Agency (EMA), WHO, AUDA-NEPAD and the African Medicines Agency (AMA).
7. Innovation and digitalisation to enhance access to medicines.
8. Managerial abilities, country leadership and ownership in complex undertakings.

These priorities deepen the MAV+ policy framework's three dimensions: a) supply side, b) demand side and the c) enabling environment for pharmaceutical systems and its six work streams: 1) industrial development, supply

[11] This section should be in line with the indicative budget in section 4.5 (e.g. the amount of the third-party contribution as co-financing of grants should not be specified)
[12] Art. 27 NDICI
[13] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway_en
[14] https://ec.europa.eu/commission/presscorner/detail/en/statement_22_3128

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.

The Action will complement ongoing efforts to facilitate production and access to vaccines in Africa through the TEI MAV+ Initiative. The EU, Member States and European financing institutions following a Team Europe (TE) approach are already offering support in countries that can demonstrate, among others, that production of vaccines and essential medicines is a political priority and Governments show strong commitment to consolidate national pharmaceutical industries and have concrete national plans to implement policy priorities.

The Action will also have a regional impact, will contribute to (and benefit from) several workstreams of the regional TEI MAV+, notably by training people from different countries and in alignment with the Partnership for African Vaccine Manufacturing (PAVM) efforts, or addressing demand for health goods, or supporting institutes in becoming regional hubs of research and production.

This Action is part of the Global Gateway investment package for Africa and supports the health priority on strengthening health systems, in particular investments to support efforts in vaccine deployment, infrastructure and production capacities, skills development, regulatory frameworks and universal health coverage as well as research. Its main goal is to contribute to the achievement of SDG 3 (Ensure healthy lives and promote well-being for all) and will impact SDG 4 (Quality Education and Lifelong Learning for all), SDG 5 (Gender Equality), SDG 8 (Decent Work and Economic growth), SDG 9 (Industry and innovation), and SDG 17 (Partnership).

Several EU Member States and private sector actors are already investing in the field of manufacturing pharmaceutical products and health technologies, with high potential for partnerships and trade. The initiative, MAV+, is a priority initiative aligned with the EU4Health initiative, the Pharmaceutical Strategy for Europe[15], Horizon Europe and the work of the Health Emergency and Response Authority.

This action relates to the priority area of Public Health of the African Union-European Union Innovation Agenda, and will contribute to its implementation. The AU-EU Innovation Agenda, adopted by the African Union and the European Union in July 2023, as one of the flagship initiatives of the Global Gateway, aims to transform and increase the innovative capacities and achievements of European and African researchers and innovators into tangible outputs, such as products, services, businesses and jobs. In the area of publich health the AU-EU Innovation Agenda proposes in particular to take action for ensuring technology transfer and improving and developing quality vaccines, medicines and health technologies and production in Africa (e.g. by favouring the development of 'thematic' start-ups and fostering private sector investment), to avoid shortage and ensure affordability, availability, and accessibility for the people in need. The AU-EU Innovation Agenda proposes as well to ensure equitable access to, distribution and fruition of innovative and sustainable health technologies across geographical areas in Africa.

The Action will help to advance the achievement of EU policy objectives, notably in areas of trade and investment and customs facilitations and intellectual property rights in the sector and countries concerned.

The Action will contribute to the realisation of the EU Gender Action Plan 2021-2025 GAP III[16], in particular to its thematic area of engagement "Promoting economic and social rights and empowering girls and women".

1.3 Zone benefitting from the Action

The Action shall be carried out in Senegal, Rwanda, Ghana, South Africa, Nigeria and Egypt. All countries are included in the list of ODA recipients. Ghana and South Africa are applying EPA with the EU since 2016, and there are potentials for Senegal, Rwanda and Nigeria to strengthen trade relations with the EU. Egypt is applying an Association Agreement with EU since 2004.

[15] https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en
[16] https://www.eeas.europa.eu/eeas/gender-action-plan-iii-towards-gender-equal-world_en

2 RATIONALE

2.1 Context

Africa imports 99% of its vaccines and over 90% of its medicines. Moreover, according to the World Health Organization (WHO), over 50% of people in sub-Saharan Africa lack access to essential medicines. Consequently, in May 2021, at the G20 Global Health Summit, President von der Leyen announced the Team Europe initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa. This was a response to the call from the African leaders who had launched the Partnerships for African Vaccine Manufacturing (PAVM) in April 2021. The TEI MAV+ is a key priority of the EU Global Gateway strategy and the EU Global Health strategy.

At continental level, the Commission is supporting the African Medicines Agency (AMA) and Africa Centers for Disease Control and Prevention (AfCDC), which hosts the Partnership for African Vaccine Manufacturing (PAVM), AUDA-NEPAD's work on the African Medicines Regulatory Harmonization (AMRH) initiative, and WHO's mRNA technology transfer programme and its access to medicines department. This continental approach ensures that no country is left behind when it comes to ensuring equitable access to health products.

The EU, Member States and European financing institutions following a Team Europe approach have reported to the Commission a total planned allocation of EUR 1.2 billion with already around EUR 980 million approved and under implementation, encompassing EUR 663.80 million in loans and other financial instruments from European Development Financial Institutions (EDFIs), and EUR 316 million in grants, budget support and blended finance.

While some interventions have a higher impact if implemented through a multi-country or continental approach (i.e. pooled procurement, demand consolidation and market shaping, regulatory harmonisation, etc.), others require a country level approach (i.e., skills development, health research systems, etc.).

Complementarily, at country level, the Commission is mainly active in countries with manufacturing potential. The EC alone has mobilised so far EUR 55.9 million combined in 4 frontrunners countries: Senegal, Rwanda, South Africa and Ghana. Resources from EFSD+ should create additional incentives.

The focus of this special measure is on country level actions to complement the regional and country actions developed so far and well aligned with countries' own plans, either in frontrunners countries, or in countries that demonstrated political willingness, technical and administrative capacity and preparation.

The EU is modernising/ deepening agreements towards trade rules such as on investment, services, IP, procurement and competition, which will help create new conducive investment climates including in the health sector in Africa countries.

2.2 Problem Analysis

Short problem analysis:
While substantial funding has been made available by the EU, Member States and European financing institutions following a Team Europe approach (EUR 1.2 billion, of which 70% comes from DFIs and additional contributions from EU Member States) in SSA, further resources are needed to deliver transformational impact and ensure long-term sustainability on the African continent. The African Union has identified a funding gap of USD 30 billion until 2040. For a smaller set of priorities, the African Development Bank has estimated a EUR 11 billion gap. To help cover unmet needs in Africa, and also reach the target of EUR 1 billion for MAV+ from the EU budget, it is necessary to mobilize additional funding from the cushion to reinforce the SSA regional and the Southern Neighbourhood budget lines.

Senegal
In October 2021 Senegal developed a comprehensive "plan for the revival of the pharmaceutical industry", costed at EUR 500 million. The Commission, EIB, BE, DE, FR and LUX following a Team Europe approach have

committed a total of more than EUR 160 million so far. Funding gaps remain in the sector regarding 1) governance and managerial abilities, 2) skills development through education and training, and 3) digitalisation, for example of the supply chain and the public administration, notably the medicines regulatory agency amongst other. The industry in Senegal currently seeks to establish new vaccine production facilities, to expand its research and training activities and benefits as a partner of WHO's mRNA technology transfer programme.

Rwanda
Contributions in a Team Europe approach so far amount to EUR 22 million (e.g., benefiting Rwanda FDA, University of Rwanda, etc.). Funding gaps are identified in 1) support to SMEs, 2) skills -higher education, TVET- and 3) quality assurance along the supply chain. The industry plans to produce drug substance starting in 2024 with modular factories to help produce novel vaccines.

Ghana
A Roadmap for Vaccine Development and Manufacturing was developed in 2021 and it is currently undergoing review under the leadership of the National Vaccine Institute in Ghana. The country has estimated its financial needs for this agenda at USD 200 million. TE's current allocation is EUR 15.9 million. Funding needs to be covered by the European Commission span the following areas: 1) R&D and skills development, 2) regulatory strengthening and 3) technology transfer. Ghana has become a frontrunner country for vaccine manufacturing in Africa hosting one of the strongest regulatory agencies on the continent. With 38 existing pharmaceutical companies and further ones coming up, it has an already thriving pharma sector to build on. Next to strong relationships with Western countries, Ghana's companies can boast successful South-South collaborations, for technology transfer, supply, skills development and research. Further strengthening market access capacities and skills would enable the country to excel further as a regional hub in this sector.

South Africa
While the National Strategy on Local Vaccine production of South Africa is still being developed, several gaps can be identified in the pharmaceutical sector. TE mobilised over EUR 400 million in South Africa, including support to SAHPRA, the regulator and industry. Funding needs for European Commission interventions are identified for 1) R&D and skills development, 2) further regulatory strengthening, including via digitalisation, and 3) to enhance demand for and supply of locally produced goods complementing continent-wide approaches. The industry in South Africa has already been producing COVID-19 vaccines, but as demand has been low it will look into producing other vaccines commonly administered in Africa (pneumococcal, polyvalent, meningococcal or rotavirus vaccines). A second manufacturing project is a public-private partnership aiming at providing fill & finish capacity, and to ensure end-to-end production.

Nigeria
TE recently mobilised EUR 46,500 to support the National Institute for Pharmaceutical Research and Development (NIPRID) to assess local manufacturing capacity readiness of the country and identify gaps, most of which under the MAV+ framework. Funding needs for European Commission interventions are for 1) R&D and skills development through education and training, 2) the digitalisation of essential dimensions of the ecosystem (supply chain, regulatory functions) and 3) support to a centralised system for forecasting, procurement, and distribution of quality medical products. The European Commission is currently also providing technical assistance to advance the government's strategy. The industry in Nigeria is particularly active (with over 115 registered pharmaceutical manufacturers). In December 2022, the EIB signed an USD 14 million loan for production of active pharmaceutical ingredients, including for treatments against malaria. Additionally, EIB has identified two private additional companies, for support.

Egypt
EU support is requested in Egypt for the strategic planning and strengthening the capacities the producing companies in addition to the regulatory authority with an initial funding need of EUR 3 million. The EU has identified Egypt as one of the countries with high potential to evolve into an effective and profitable hub for pharmaceutical production. This is based on Egypt's strong geographic, development and manufacturing position enabling it to contribute significantly to the continent's aspirations to greater autonomy in medicinal products. Besides this, Egypt could act as a source of help and inspiration for many African countries in this respect. Egypt has also been selected among the first six recipients of technology from the WHO's global mRNA vaccine hub and has a well-developed regulatory authority which could be eligible for inclusion into the transitional WHO Listed

Authorities.

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

Dozens of countries have expressed interest in local manufacturing of biologicals and pharmaceuticals. Only a few manufacturing sites of vaccines and medicines can be viable on the continent in the long run and diversification of production is essential, as well as complementarities along the value chain. Progress to ratify the African Medicines Agency (AMA) Treaty will be considered as a positive indication of the country's commitment.

Further assessments and consultations are needed to determine the transformative potential of EU action in these countries and the exact funding needs that may alter the final distribution among countries.

Key public stakeholders are the Ministries of Economy, Health or Education or Research, countries' national regulatory authorities (NRAs), universities, research centres and institutes, African institutions, other donor countries, and NGOs and private sector -both local and international.

3 DESCRIPTION OF THE ACTION

3.1 Objectives and Expected Outputs

The Overall Objective of this action is to support sustainable implementation of the national plans in order to increase local manufacturing of health products and equitable access for the population and contribute to the delivery of the Global Gateway strategy and Global Health Strategy.

The Specifics Objectives of this action are to:

1. Support the enabling environment for local pharmaceutical and health technologies production through Research & Development and developing skills (managerial abilities, higher education and vocational training (TVET)) (Senegal, Rwanda, Ghana, South Africa, Nigeria, Egypt).
2. Support industrial development, supply chain management and integrity, including digitalisation (Rwanda, Nigeria, South Africa, Senegal).
3. Strengthen the regulatory environment in countries in view of complementing regional level regulatory support (Ghana, South Africa, Egypt, Senegal, Rwanda).
4. Promote technology transfers, licensing, and intellectual property management (Ghana).
5. Support demand and supply of locally produced goods including forecasting, procurement and distribution of health products in view of complementing regional level efforts (South Africa, Nigeria, Egypt).

The Outputs to be delivered by this action contributing to the corresponding Specific Objectives are:

1.1 contributing to Outcome 1 (or Specific Objective 1): Strengthen governance, coordination mechanisms and managerial abilities from a government perspective in Senegal, Nigeria and Ghana.
1.2 contributing to Outcome 1 (or Specific Objective 1): Address human resource gaps and capacities, higher education and vocational training, considering a gender and disability-sensitive approach, for core and auxiliary functions linked to the production of human medicines and vaccines, and stimulate R&D in Rwanda, South Africa, Egypt, in Senegal, Ghana and in Nigeria. In that respect, complementarity will be sought with the Erasmus+ programme which supports the mobility of staff and students between European and African universities and capacity building projects in the Higher Education ans VET fields, in a Team Europe spirit.

1.3 contributing to Outcome 1 (or Specific Objective 1): Support the emergence of a biotech start-up ecosystem in Rwanda, development of pharma value chain and facilitate the creation of a robust pharmaceutical industrial ecosystem in South Africa, Senegal and in Ghana.

2.1 contributing to Outcome 2 (or Specific Objective 2): Build resilient pharma supply chains through digital

transformation in Senegal and Nigeria.
2.2 contributing to Outcome 2 (or Specific Objective 2): Strengthen the supply chain/logistics in Rwanda and Nigeria with a focus on quality assurance.
2.3 contributing to Outcome 2 (or Specific Objective 2): Provide innovative access to finance and guarantees for nascent and established enterprises in South Africa along the pharma value chain.

3.1 contributing to the Outcome 3 (or Specific Objective 3): Enhance and consolidate the technical assistance to the Regulatory Authority in order to build further capacity to be regional centre of excellence in Ghana and South Africa.
3.2 contributing to Outcome 3 (or Specific Objective 3): Strengthen the technical capacity of the Egyptian Drug Authority to become WHO Listed Authority for Vaccines and Medicines.
3.3. contributing to Outcome 3 (or Specific Objective 3): Enhance the structures and processes for lot release of vaccines and biologics in Ghana and Rwanda.
3.4 contributing to Outcome 3 (or Specific Objective 3): Strengthen Ghana FDA's capacity as a Centre for Regional Excellence in Africa.

4.1 contributing to Outcome 4 (or Specific Objective 4): Facilitate networking and building of strong international partnerships for technology transfer according to the WHO guidelines on technology transfer in pharmaceutical manufacturing including support for licensing and intellectual property management in Ghana.

5.1. contributing to Outcome 5 (or Specific Objective 5): Improve the technical capacity of South African actors to conduct market analyses and design market-shaping measures for vaccines produced in South Africa.
5.2 contributing to Outcome 5 (or Specific Objective 5): Strengthen the Egyptian and Nigerian authorities strategic planning of the industrial development of Vaccines and Biologicals, including domestic production and export.

3.2 Indicative Activities

SENEGAL

The Action will support further the implementation of the Senegalese national plan for the revival of the pharmaceutical industry aiming at pharmaceutical sovereignty, with the objective of producing locally 50% of local needs by 2035. It supports an enabling environment for local pharmaceutical and health technologies production in Senegal (and in particular for MADIBA, a project led by Institut Pasteur de Dakar to develop vaccine manufacturing facilities), notably through targeted support to governance and coordination mechanisms, TVET, higher education, R&D, local industries, and the digitalisation of essential dimensions of the ecosystem (supply chain, regulatory functions).

The project approach might be combined with a second phase of "public policy financing" to enhance the political dialogue and push key activities or reforms contributing to Outcome 1, 2 and 3.

Activities related to Output 1.1
1.1.1 Support to the functioning of the Delivery Unit and the inter-ministerial committee
1.1.2 Support for key reforms (e.g., pharmacopeia reform, training reforms, supply chain reform, energy price reform etc.)
1.1.3 Support a stronger representation of SN authorities in regional fora on vaccine and pharma production to consolidate Senegal strategic subregional positioning and foster regional collaboration in the regulatory area
1.1.4 Support to additional reform drivers such as the Ministry of Economy, Cooperation and Planning and the Ministry of Industrial Development, including their respective reforms.

Activities related to Output 1.2
1.2.1 Develop coherent frameworks and strategies for talent development and R&D between the three main responsible ministries, namely the Ministry of Health (MSAS), the Ministry of Vocational Training (MFPAI) and the Ministry of Higher Education (MESRI), in close consultation with education providers and the private sector
1.2.2 Consolidate the comprehensive mapping for TVET and Higher Education (university and post university)

offer and needs
1.2.3 Update the curricula and developing capacities of teaching staff for existing and/or further education and training programmes for selected priority professions, promoting professional-women participation
1.2.4 Launch a TVET programme for the pharmaceutical sector (taking an inclusion approach), for instance a dual vocational training for pharmaceutical production specialists in cooperation with local companies
1.2.5 Initiate University degrees (Licence/Master/Doctorat) on pharmaceuticals sciences at regional level
1.2.6 Initiate continuing training courses for health professionals and professors meeting market needs validated at regional level
1.2.7 Initiate professional training
1.2.8 Promote industry internships, encouraging women and persons with disabilities participation as possible
1.2.9 Contribute to a regional hub for training and competence development in pharmaceutical value chain for the region
1.2.10 Link Senegalese institutions with other academic and technical institutions in Africa and Europe as well as with research networks to develop R&D projects
1.2.11 Foster Senegal expertise to apply for research grants (EDCTP and others)
1.2.12 Develop and implement a research capacity development program according to priority needs and gaps

Activities related to Output 1.3
1.3.1 Deepen the existing "Plan for the revival of the pharmaceutical industry" by developing a coherent and impactful national strategy which identifies specific market opportunities for Senegalese companies
1.3.2 Initiate a call for proposals for entrepreneurship, innovation and local production
1.3.3 Develop private sector collaboration projects with Senegalese and European companies
1.3.4 Strengthen existing business associations and public-private co-creation of ecosystem development
1.3.5 Facilitate access to finance for pharmaceutical companies, amongst others by sectorial market studies and specific support programmes for companies and financial institutions
1.3.6 Verify the necessity and feasibility of a pharmaceutical industrial zone

Activities related to Output 2.1
2.1.1 Implementing ARP (*Agence de Réglementation Pharmaceutique*)'s serialization project in order to address the threat of substandard and falsified products and boost confidence in local goods
2.1.2 Improving the supply chain and inventory management

RWANDA

The overall objective of the action is to strengthen Rwanda's pharmaceutical and biotechnology sectors through targeted support to entrepreneurship, higher education, TVET, and logistics/supply chain.

Activities related to Output 1.2 (non-exhaustive)
1.2.1 Support the design and set-up of a biotechnology institute in Rwanda
1.2.2 Support the identification and/or set-up or consolidation of adequate MSc and PhDs, within relevant universities in Rwanda, in cooperation with European universities
1.2.3 Support to establish university cooperation on research, and in particular on clinical trials, liaising with the public health institute (Rwanda Biomedical Centre) and the Rwanda Food and Drug Authority
1.2.4 Support an in-presence and digital training offer for bio-production (for initial training, upskilling or continuous learning purposes) encouraging women to participate in training, including the use of digital twins for factories or virtual reality, building on existing European training offer
1.2.5 Support to develop tailor-mode TVET modules, courses and new trades (if required) aligned with the needs of the industry, focused on the skills required for the workforce in pharmaceutical and biotechnological production, encouraging women and persons with disabilities participation as possible
1.2.6 Support to strengthened TVET teacher training
1.2.7 Support to strengthen overall quality management in TVET (quality standards)

Activities related to Output 1.3 (non-exhaustive)
1.3.1 Expand the offer of the Rwanda Bioeconomy Skills Development and Acceleration Centre to be set-up either by a) providing equipment for the laboratory space, b) setting up a seed capital fund and c) providing additional

business development services, or a combination of all these

Activities related to Output 2.2 (non-exhaustive)
2.2.1 Support to Rwanda Medical Stores (RMS) to reach ISO 9001:2015 certification, including support for quality management, quality data collection support (end to end) and use of digital tools
2.2.2 Support integration of national EPCIS system in RMS systems including rapid alert system

Activities related to Output 3.3 (non-exhaustive)
3.3.1 Provision of equipment needed to perform lot release to the Rwanda FDA Quality Control Lab

GHANA

The Action will support the enabling environment for pharmaceutical products and health technologies in Ghana, notably: i) the research, clinical trials and innovation area; ii) the further upgrading of capacities of the Food and Drugs Authority (FDA) to regulate the authorisation and use of these products; iii) the development of skills needed by the bio-pharmaceutical industry in Ghana and within the continent; iv) technology transfers, licensing and intellectual property management; v) trade and investment and customs facilitation measures and IPR frameworks and conditions and enabling environment for preferential trade and investment.

Activities related to Output 1.1 (non-exhaustive)
1.1.1 Support to governance institutions and coordination mechanisms to regulate and coordinate the pharmaceutical sector in Ghana, including Departments of the National Vaccine Institute, the FDA, research institutions and the National Trade Facilitation Committee, Ministry of Health and Ministry of Finance.

Activities related to Output 1.2 (non-exhaustive)

1.2.1 Support the Department of Research and Development of the National Vaccine Institute to strengthen its coordinating and oversight function
1.2.2 Support regional and international scientific fora for vaccine R&D to network and share ideas
1.2.3 Support Ghanaian research institutions with laboratory upgrades, equipment needed for scaling-up bio-medical research and training and capacity building institutions on basic research on development of pharmaceutical products in Africa
1.2.4 Support to Ghanaian research institutions in the field of pharmaceutical and vaccine production via trainings for researchers
1.2.5 Support the establishment of a Bioequivalence centre to strengthen the local production of quality vaccines and other pharmaceutical products in Ghana.

Activities related to Output 1.3 (non-exhaustive)

1.3.1 Support to the Department of Manufacturing (Regulation, Market Shaping and Trade) of the National Vaccine Institute to strengthen its coordinating and oversight function
1.3.2 Support to pharmaceutical companies in Ghana to render their businesses sustainable and sustain and create jobs

Activities related to Output 1.4 (non-exhaustive)
1.4.1 Support to the Department of Human Capacity Development of the National Vaccine Institute to strengthen its coordination and oversight function
1.4.2 Support and implement a TVET program for machine operators in the pharma manufacturing sector
1.4.3 Support the establishment and operationalization of the Kina Foundation Biomanufacturing Institute
1.4.4 Implement a training course on career development in the Ghanaian and African pharmaceutical sector

Activities related to Output 3.1 (non-exhaustive)
3.1.1 Support the Department of Manufacturing of the National Vaccine Institute to strengthen its coordination and oversight function for regulation, market shaping and trade

3.1.2 Support to enhance the regulatory competences of pharmaceutical manufacturers in Ghana
3.1.3 Support the Food and Drugs Authority's capacity to achieve digital international standards for regulatory processes
3.1.4 Support the set-up and equipping of a Molecular Biology Laboratory for the Food and Drugs Authority.

Activities related to Output 3.3 (non-exhaustive)

3.3.1 Support the development and implementation of processes and structures for lot release of vaccines and biologics in Ghana.

Activities related to Output 3.4 (non-exhaustive)
3.4.1 Support the regulatory capacity for regulators in the African sub region through support to the Ghana FDA.
3.4.2 Support the FDA to enhance their regulatory capacity.

Activities related to Output 4.1 (non-exhaustive)

4.1.1 Support the Department of Funds and Partnerships of the National Vaccine Institute to strengthen its coordinating and oversight function.
4.1.2 Support to relevant institutions to undertake study trips and exchange programmes to relevant hubs for vaccine manufacturing.
4.1.3 Support and facilitate exchanges between Ghanaian and European, African and Asian countries.
4.1.4 Support better transparency of the investment conditions, streamline authorisations for investment, e-government, better public-private dialogues in the pharma sector.

SOUTH AFRICA

The Action will support the development of an enabling environment for local pharma value chain in South Africa, enhancing the country's pandemic preparedness as well as contributing to job creation and inclusive growth notably through targeted support for i) skills development for R&D and TVET, ii) the implementation of the National Local Vaccine Production Strategy as well as the regulatory authority, SAPHRA, possibly for improving its pandemic preparedness and iii) ensuring supply and demand for locally produced goods through regulatory or other incentives to procure products manufactured in South Africa, complementing continental and regional level actions.

Activities related to Output 1.2 (indicative- non-exhaustive)
1.2.1 Support establishment of a Center of Excellence for young and mid-career scientists, building up on the tandem programme EDCTP has piloted, liaising with the SAHPRA Regulatory Authority, South African Medical Research Council, EDCTP Africa Office. The center can also provide technical assistance to researchers to participate in peer-to-peer learning, further training, and networking opportunities and exchanges with European and African institutions and companies i.e., match-making events, conferences, or online platforms where projects can share their progress, exchange ideas, and seek advice from peers working on similar topics.
1.2.3 Support establishment/revitalisation of a SETA in the healthcare products/pharma production sector to develop tailor-mode TVET modules for support functions aligned with the needs of the value chain.
1.2.4. Design, plan, and launch a competitive call for proposals of innovative research projects on vaccine development. This indicative activity could be tailored specifically for consortia consisting of universities and private sector stakeholders in the biotechnology industry and other related industries. By fostering collaborations between academia and industry to undertake joint research and development projects related to vaccine development, specific gaps and challenges can be addressed.
1.2.5 Provide technical assistance to the selected innovative research projects by providing tailor-made training programs.
1.2.6 Facilitate access to specialized resources that can support the technical aspects of the research projects. This may include providing access to cutting-edge laboratory facilities, equipment, software tools, databases, or other relevant resources.

Activities related to Output 1.3.
1.3.1. Provide financial, technical and policy support to local manufacturers on sustainable business modelling: i.e. expert support for successful application to apply for GAVI funding (flanking of multilateral funding).
1.3.2. Identify and support value-chain and ecosystem actors through capacity building in the form of technical assistance, access to local and international market opportunities through B2B matchmaking and pitching events.

Activities related to Output 2.3.
2.3.1 Support the Biovac Institute's facilities expansion plan with a blending grant to produce Cholera vaccines
2.3.2 Establish a financial and business development facility and scaling opportunities managed by a pillar assessed DFIs (EIB, IFC or FMO) present in South Africa that support nascent SMMEs in the VCs' access to finance by providing them with business development services, working capital and loans and by attracting funding from DFIs, commercial banks or the private sector.

Activities related to Output 3.1.
3.1.1. Digitalization of paper-based pharmacovigilance processes and surveillance activities to improve SAHPRA's efficiency as well as training of SAHPRA staff on newly introduced digital tools. (Strengthen pharmacovigilance unit and post-marketing surveillance activities).
3.1.2. Capacitate SAHPRA's pharmacovigilance unit as well as laboratory staff to evaluate a larger number of medicinal samples, for example through training and support to define guidelines and efficient standard operating procedures. (Strengthen pharmacovigilance unit and post-marketing surveillance activities).
3.1.3. Technical support to evaluate relevant policies and processes for the emergency use of unregistered medicines in South Africa to support the country's regulatory preparedness and capacities to respond to future pandemics. (Pandemic Prevention and Response).
3.1.4. Partnering with the Department of Science and Innovation towards the implementation of their upcoming strategy on research, development and vaccine manufacturing in the form of technical assistance and pilot project development.

Activities related to Output 5.1.
5.1.1. Elaboration of concrete price differential analysis for different new vaccines produced in South Africa (i.e. oral cholera vaccine, pneumococcal conjugate vaccine, measles).
5.1.2. Facilitation of evidence-based dialogue among different stakeholders (private sector, government, international funds and donors) on generating demand for sustainability of the pharma value chain by elaborating on various solutions such as cost splitting.

NIGERIA

The Action will support further the implementation of Nigeria's national plan for the revival of the pharmaceutical industry and local production capacity of vaccines and medical technologies based on enhanced research and development capacities. The Action will support an enabling environment for research and development as well as local pharmaceutical and health technologies production in Nigeria notably through: (i) **skills development** through education and training, (ii) **research and development** (e.g. research in artificial intelligence and nanotechnology); (iii) the **digitalisation** of essential dimensions of the ecosystem (supply chain, regulatory functions) and (iv) support to a centralised system for **forecasting, procurement and distribution** of quality medical products; v) trade and investment and customs facilitation measures and IPR frameworks and conditions and enabling environment for preferential trade and investment. The Action will be implemented in Nigeria, a country with a solid pharmaceutical landscape and an indispensable partner for the continent from a value chains perspective.

Activities related to Specific Objective 1 - Skills development and Research, promoting women and persons with disabilities participation as possible.

- Training programmes: collaborate with local universities, vocational institutes and industry experts to design and implement specialised training programmes that focus on pharmaceutical manufacturing, quality control, regulatory compliance, and other relevant skills required for vaccine and medical product

production.
- Scholarships and Grants to aspiring students and professionals in the field of pharmaceutical sciences and engineering.
- Internship Programmes: Establish partnerships with local pharmaceutical companies and invite students to participate in internships for practical hands-on experience and exposure to real-world manufacturing processes.
- Collaborative research projects by encouraging partnerships between local research institutions, universities, and pharmaceutical companies.
- Support legal and regulatory environment for harmonised policy adoption .
- Support development of a unified policy for procurement.
- Support procurement, licensing and/or manufacturing of drug substance (APIs).
- Support and enabling environment for formulation and manufacturing.

Activities related to Specific Objective 2 – Digitalisation and support to supply chain

- Facilitate technology transfer from established international pharmaceutical companies to local manufacturers through partnerships, knowledge sharing, and technical assistance programmes.
- Support investment in development of digital infrastructure required for efficient manufacturing process, quality control, supply chain management, and regulatory compliance including support for implementation of robust information systems, data analysis tools, and process information.
- Support establishment of an efficient centralised procurement system.
- Support procurement and or manufacturing of raw materials and supplies.
- Support development of a centralised system for forecasting, procurement and distribution to mitigate risks of supply chain failures and stockouts.
- Support fill and finish manufacturing and Glass Vial manufacturing.
- Support Shipment distribution.
- Support Cold Chain Storage.
- Support Packaging and Lot release.

Activities related to Specific Objective 5 - Demand and supply

- Support needs assessment of states and their populations.
- Support market analysis for vaccine procurement and manufacturing.
- Provide training and support to selected procurement agency(cies) and local manufacturers in areas such as procurement processes, contract management, quality assurance, and regulatory compliance.
- Support local manufacturers to meet international quality standards and regulatory requirements, enabling them to participate in regional and global procurement opportunities.

Support better transparency of the investment conditions, streamline authorisations for investment, e-government, better public-private dialogues in the pharma sector.

EGYPT

The action will focus on the below:

Activities related to Output 1.2.

1.2.1 support capacities of manufacturing companies in reaching the WHO Pre-Qualification Level for several products produced in their facilities. This will help to increase their exposure to the different markets, mainly the African one; iv) development of collaborations between academic groups and industrial companies to develop new products and to industrialise academic research.

Activities related to Output 3.2.

3.2.1 strengthening the capacities of the EDA in different domains through a twinning project, including but not limited to the regulation of biologicals, extending the maturity of the agency to Level 4 and towards becoming a WHO listed authority. This would widen the recognition of EDA's decisions and approved products, and help EDA in building regulatory harmonisation on biologicals within Africa through the newly established African Medicine Authority (AMA).

Activities related to Output 5.2.
5.2.1 Developing a National Strategy for Vaccines and Biologicals, covering domestic production and export. Such a strategy would cover licensing needs, manufacturing capacity, national demand, export needs, as well as competitiveness, among other areas. The strategy would allow the industry to better focus its efforts in these areas and would inform public policy, including those to foster a favourable ecosystem.
The commitment of the EU's contribution to the Team Europe Initiatives foreseen under this action plan will be complemented by other contributions from the partners applying a Team Europe approach. It is subject to the formal confirmation of each respective partners' meaningful contribution as early as possible. In the event that the TEIs and/or these contributions do not materialise the EU action may continue outside a TEI framework.

3.3 Mainstreaming

Environmental Protection & Climate Change
N/A

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

Nevertheless, on March 2019, the Commission adopted a strategic approach to pharmaceuticals in the environment as required by Article 8c of Directive 2008/105/EC as amended by Directive 2013/39/EU. The approach covers all phases of the lifecycle of pharmaceuticals, from design and production through use to disposal. This will guide the exchanges with partners on these matters, 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 participation, human rights-based approach, 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[17]. 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. As well, the specialised training and TVET programmes delivered by this initiative, will consider a gender-sensitive approach.

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 organizations (UN Women, UNDP, WHO) and can be helpful during implementation of the action.

Indicators will be disaggregated to account for gender objectives and, when possible, other cross-cutting issues.

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

Local authorities and civil society could be involved when addressing gender balance and ethics in research, youth, workforce and inequalities.

Human Rights

Access to medicines and vaccines is a human right. Implementing the initiative will stimulate economic growth and decent work in different countries, while advancing universal health coverage (UHC) and human development. The action will apply a human rights-based approach by respecting the following principles: respect to all human rights, participation, non-discrimination, accountability, and transparency in all phases. Special supports from gender and human rights experts will be included during the implementation phase for analyses and studies, whenever relevant.

Disability

This action is labelled as D1. Recently disaggregated data collection on disability was carried out in Africa including by World Bank[18] and Disability Data Initiative[19]. More data collection is planned in some targeted countries[20] which can be used for planning targeted activities.

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. 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. The action will 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.

Local authorities and civil society could be involved when addressing gender balance and ethics in research, youth, workforce and inequalities. Organisations of persons with disabilities will be consulted and involved during planning, implementing and monitoring relevant activities, when relevant.

Reduction of inequalities

The objective of the 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 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 most vulnerable.

Equal job creation opportunities and digital opportunities will be created, particularly for the youth, in the pharmaceutical sector. Youth will also benefit through education and training. The activities will contribute in the end to health security and preparedness for future health pandemics, that will benefit to the most vulnerable. Working on demand for health goods will allow better understanding inequality drivers across population groups and countries.

Local authorities and civil society could be involved when addressing gender balance and ethics in research, youth, workforce and inequalities.

Democracy

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.

Conflict sensitivity, peace and resilience

The action will promote health systems resilience, pandemic preparedness and global health security. Populations

[18] https://www.worldbank.org/en/topic/poverty/brief/challenges-facing-people-with-disabilities-in-sub-saharan-africa-in-5-charts

[19] https://disabilitydata.ace.fordham.edu/summary/

[20] https://www.sightsavers.org/news/2022/12/senegal-launches-action-plan-to-collect-inclusive-data/

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	*Changes in political context or in countries' health priorities. Misalignment in terms of general culture and position of these countries when coming to governance issues in public health*	***Medium***	***High***	*Political commitment is tested along the implementation phase and, eventually, policy dialogue is used to, amongst others, remind partners of policy commitments taken earlier by them Understanding and taking into account specific culture and position of countries when coming to governance issues in public health.*
People and the organization	*Difficulties of coordination due to cross-cutting activities (education, research), multiple partners, similar initiatives*	***Medium***	***High***	*Ensuring increased coordination of Team Europe Initiative at strategic and operational level through the High-Level Steering structure (EU-AU), the EU Member States Task Force and the other members of the TEI-MAV+ Management Team, and the Team Europe Support Structure (TESS) implemented by Enabel, GIZ and Expertise France.*
Planning, processes and systems	*Low national resources (financial, infrastructure,*	***High***	***High***	*Use this action to pool resources (financial and technical), and advocate for countries to invest in pharma systems,*

	human) made available by African countries' governments to guarantee the success of the local manufacturing agenda.			*including public procurement of locally produced goods.*
Planning, processes and systems	*Several organisations, MS and EC Services are working in research and innovation, there is a risk of overlap*	***Medium***	***Medium***	*The Commission services responsible for research 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.*
External environment	*Risks related to adverse private sector and business environment*	***High***	***High***	*TEI-MAV+ is a comprehensive TEI that includes specific workstreams facilitating businesses in the pharmaceutical sector, such as regulatory and market shaping. Under these workstreams, support actions are build to address various barriers to private sector, for example regarding health products' authorisation, access to market, pricing, access to finance and availability of skilled staff.*
Political system	*Changes in key personnel of public institutions and uncertain political commitment*	***Medium***	***Medium***	*National documents, such as Roadmap on and Strategies on local vaccine and medicines manufacturing, provide guidance on the implementation process. Potential support to the National Vaccine Institutes can enhance their coordination role and oversight on vaccine related issues in countries.*
Planning, processes and systems; and political systems	*The changes created in countries as a result of the activities covered by this action are not sustainable and cannot maintain a long-term impact.*	***Medium***	***Medium***	*Broad consultation with stakeholders. Ensuring support from and signing financing agreements with countries' governments. Period of implementation is long enough to follow the developments. Nature of activities, many of them targeting activities meant to increase sustainability of manufacturing and access, notably research, skills and demand of health products.*

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 long-term production process, large number 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 scarce.

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, 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.

There are other areas of research funded by the EU that bring EU and African health organisations closer together. The EU-Africa PerMed project that integrates African countries into activities of the International Consortium for Personalised Medicine (ICPerMed) contributes to the implementation of personalised medicine in the global context, fostering joint projects and programmes between Europe and Africa and strengthening bilateral EU-African Union

science, technology and innovation in health.

The European Medicines Agency (EMA), in cooperation with the World Health Organization (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 Industrialization 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 Organization (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 authorization of medical products. 11 Regional Centres of Regulatory Excellence (RCOREs) have been designated to serve as sustainable structures for increasing regulatory workforce in Africa using existing academic institutions and NRAs. 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 immunization vaccines will be produced locally and sustainably by 2040.

3.5 The Intervention Logic

This action aims to support a sustainable implementation of the national roadmaps and plans of six African countries in order to increase local manufacturing of health products and equitable access for the African population. The production of highly qualified health products has several challenges though: 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 long-term production process. Therefore, the main outputs revolve around the following priorities identified to ensure a sustainable manufacturing ecosystem in Africa: 1) skills development, 2) private sector, 3) quality assurance along supply chains, 4) research and development (R&D), 5) technology transfer, 6) regulatory strengthening, 7) innovation and digitalisation and 8) managerial abilities. These priorities guide the action's activities and result in five specific objectives as a means to achieve the overall objective.

Skill development and R&D are crucial factors to create an enabling environment for local pharmaceutical and health technologies production (Specific Objective 1). In coordination with continental efforts (i.e., PAVM) and building on a gap assessment, the action would look at supporting the identification and/or set-up of adequate MSc or PhDs in cooperation with several European universities and building on previous experiences. The action will also provide support to establishing university cooperation on research. This would allow countries to be better positioned to benefit from future EDCTP (Horizon Europe) calls. The action will also look at the possibility of supporting a digital training offers building on existing European trainings.

Furthermore, industrial development and resilient supply chains (Specific Objective 2) are needed. Supply chains must be connected seamlessly to deliver the products in time, especially under pressure of a crisis, and should ensure a high quality. Here, digitalisation can play a significant role. To achieve this, countries will be supported in facilitating technology transfers between international and local players, in the development in digital infrastructures required for efficient manufacturing processes, quality control and supply chain management, and in logistical matters such as cold chain storage or Packaging and lot release. Technology transfer, licensing, and intellectual property management will be facilitated (Specific Objective 4) by networking and building of strong international partnerships according to the WHO guidelines in pharmaceutical manufacturing.

Specific Objective 3 aims to strengthen the regulatory environment in countries in view of complementing regional level regulatory support from the African Medicine Authority (AMA) which the European Commission is already supporting. The importance of regulatory strengthening and harmonisation was highlighted by the Pharmaceutical Manufacturing Plan for Africa (PMPA). This will be done by further supporting national regulatory agencies and increased investments in digital infrastructures to help with regulatory compliance.

Finally, the action will improve technical capacities to conduct market analyses and design market-shaping measures for vaccines while also strengthening the countries' authorities' strategic planning of industrial development of health products to support demand and supply of locally produced goods (Specific Objective 5). With this, the action covers all of the three MAV+ policy framework's dimensions (supply side, demand side and enabling environment for pharmaceutical systems) to facilitate production and access to health products in Africa.

As there is a risk that the action does not make sustainable changes there will be a broad consultation with stakeholders throughout the action's implementation period which will also allow to follow up on developments. It will furthermore ensure support from and sign financing agreements with countries' governments. In this regard, the action will be used to pool resources (financial and technical), to advance on coordination in a Team Europe approach, and to advocate for countries to invest in pharma systems, including public procurement of locally produced goods. Finally, many of targeting activities are exactly meant to increase sustainability of manufacturing and access as explained above, notably research, skills and supporting demand of health products.

It will also benefit from the Hight level steering structure (HLSC) set up in 2023 to coordinate health-related initiatives and programmes in the context of the AU-EU partnership on health, starting with MAV+. Its composition will be defined by the AU and the EU in equal proportion. The HLSC will be an important vehicle for dialogue between Africa and Europe and to promote African ownership of all MAV+ initiatives.

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.

PROJECT MODALITY (3 levels of results / indicators / Source of Data / Assumptions - no activities)

Results	**Results chain (@): Main expected results (maximum 10)**	**Indicators (@): (at least one indicator per expected result)**	**Baselines (values and years)**	**Targets (values and years)**	**Sources of data**	**Assumptions**
Impact	To *support the sustainable implementation of national plans for increasing local manufacturing of health products and equitable access for the population.*	% of population in Africa with access to essential vaccines/medicines (disaggregated by product, country, location and gender)	To be set at country level once operative	10 points increase from baseline value (depending on product) in selected countries by 2028	1 WHO/HAI methodology to generate reliable information of the price, availability, and affordability of selected essential medicines 2 World Bank databank 3 Internal monitoring systems of the TEI.	*Not applicable*

Outcome 1	*the environment for local pharmaceutical and health technologies production is strengthened through research, higher education and skills activities*	1.1 Number of MSc/PhD degrees granted disaggregated by gender 1.2 Number of TVET programmes successfully completed disaggregated by gender 1.3 Number of joint EU-African research projects concluded	1.1 – 0 (2023) 1.2 – 0 (2023) 1.3 – 0 (2023)	1.1 TBC 1.2 TBC 1.3 TBC	Internal monitoring systems of the TEI.	
Outcome 2	*health industry, supply chain management and integrity, including digitalisation are strengthened*	2.1 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 2.2 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) 2.3 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.	2.1 – 0 (2023) 2.2 – 0 (2023) 2.3 – 1 (2023)	2.1 TBC 2.2 TBC 2.3 TBC	Internal monitoring systems of the TEI. Implementers, companies supported, and publicly available data (e.g. AU, Ministries of Health).	

Outcome 3	*the regulatory environment is strengthened and complementary to regional level support*	3.1 Number of joint inspections 3.2 Number of manufacturing sites having received Good Manufacturing Practice (GMP) certificates. 3.3 Number of manufacturing sites having a gender policy and disability inclusion policy 3.4 Number of sites having received Good Laboratory Practice (GLP) certificates.	3.1 Not established 3.2 – 0 (2023) 3.3 – 0 (2023) 3.4 – 0 (2023)	3.1 TBC 3.2 – TBC 3.3 – TBC 3.4 – TBC	3.1 WHO/World Bank/ AU-PAVM 3.2 AUDA-NEPAD 3.3 TEI structure 3.4 WHO/AU	
Outcome 4	*the technology transfers, licensing, and intellectual property management are increased*	4.1 Number of technology transfer hubs operative in SSA 4.2 Number of new technologies introduced	4.1 – 1 (2023) 4.2 – 0 (2023)	4.1 – TBC 4.2 – TBC	4.1 WHO/AU-PAVM 4.2 WHO/AU-PAVM	
Outcome 5	*the demand for locally produced goods including forecasting, procurement and distribution of quality medical products is assessed and increased.*	5.1 Number of locally produced health goods (e.g., vaccines) being procured by African or international funds (with EU support)	5.1 – 0 (2023)	5.1 – TBC	5.1 Internal monitoring of TEI	

Output 1 **relating to Outcome 1**	1.1 Governance, coordination mechanisms and managerial abilities from a government perspective in Senegal, Ghana and Nigeria strengthened.	1.1.1 Number of governance and coordination mechanisms supported in Ghana and functioning, e.g. the 4 departments of the National Vaccine Institute, the FDA, the research institutions and the National Trade Facilitation Committee, MoH and MoF 1.1.2 Number of governance processes supported towards enabling a legal and regulatory environment for harmonised policy adoption in local manufacturing of vaccines and medical products	1.1.1 0 (2022) 1.1.2 0	1.1.1 4 per year 1.1.2 1-2 per year	1.1.1 Meeting reports 1.1.2 Progress reports, NIPRD newsletters	Institutional coordination among relevant institutions. Government commitment to local manufacture sustained Government policy on integration of Traditional Medical Practitioners (TMPs) is sustained

Output 2 **relating to Outcome 1**	1.2 Development of human capacities, higher education and vocational training to fill human resource gaps for core and auxiliary functions linked to the production of human medicines and vaccines, and stimulate R&D in Egypt, Rwanda, Nigeria, South Africa and Ghana.	1.2.1 Number of HR functions been assessed in the production of Pharma Companies produce human medicines and vaccines in Egypt 1.2.2 Number of new MSc programmes established in Rwanda 1.2.3 Feasibility study for biotechnology institute in Rwanda completed 1.2.4 TVET quality managemet module established in Rwanda disaggregated by group targeted, gender targeted, disability targeted, income and place of residence 1.2.5 Number of Ghanaian research institutions that have increased their human and physical capacities to conduct research in pharmaceutical and vaccine production by 20%. 1.2.6 Number of collaborative research projects established in Nigeria between local research institutions, universities and pharmaceutical companies 1.2.7 Number of Phytomedicine Training Conferences held for capacity building of Traditional Medicine Practitioners (TMP) towards improved contribution to the health care delivery system. 1.2.8 Number of persons trained and certified through different training programmes supported by the project in Ghana 1.2.9 Number of courses offered on pharmacovigilence supported by the project in South Africa 1.2.10. Number of African researchers on exchange programme supported by the project in South Africa 1.2.11. Number of exchanges between CoE and national and regional partners on Good Pharmacovigilance Practices in the region in South Africa 1. 2.12. Number of new research and training projects relevant to the pharma sector have been deployed by partner institutions and implemented in a gender sensitive manner in South Africa	1.2.1 0 1.2.2 0 1.2.3 No 1.2.4 No 1.2.5 capacity survey at 3 research institutions 1.2.6 0 1.2.7 0 1.2.8 0 1.2.9 0 1.2.10 0 1.2.11 0 1.2.12 0	1.2.1. 8 1.2.2 2 1.2.3 Yes 1.2.4 Yes 1.2.5 Survey at 3 research institutions to assess capacity increase 1.2.6 5 1.2.7 4 1.2.8 300 1.2.9 tbc 1.2.10 tbc 1.2.11 tbc 1.2.12 tbc	1.2.1 Government, WHO and world Bank health reports 1.2.2 Progress report 1.2.3. Progress report 1.2.4 Progress report 1.2.5 Baseline and end of project capacity survey 1.2.6 Progress report 1.2.7 Project implementation and government reports 1.2.8 Progress report 1.2.9 Progress report 1.2.10 Progress report 1.2.11 Progress report 1.2.12 Progress report	

Output 3 **relating to Outcome 1**	1.3. Emergence of a biotech start-up ecosystem in Rwanda, and development of pharma value chain in South Africa and facilitate the creation of a robust pharmaceutical industrial ecosystem in Senegal and in Ghana supported.	1.3.1 Number of start-ups supported for biotech business acceleration through the Rwanda Bioeconomy Skills Development and Acceleration Centre 1.3.2 Number of biotech business start-ups receiving seed capital through the Rwanda Bioeconomy Skills Development and Acceleration Centre 1.3.3 Number of pharmaceutical companies in Ghana that received support to improve their business 1.3.4. Number of biotech/pharma startups that received technical support for capacity development through project in South Africa 1.3.5. At least one South African Manufacturer received support to apply for Gavi funding or alike (for flanking of multilateral funding)	1.3.1 0 1.3.2 0 1.3.3 2 1.3.4 0 1.3.5. 0	1.3.1 20 1.3.2 10 1.3.3 10 1.3.4. tbc 1.3.5. 1 (end of project)	1.3.1 Progress report 1.3.2 Progress report 1.3.3 Progress report 1.3.4. Progress report 1.3.5 Progress report	
Output 1 **relating to Outcome 2**	2.1 Resilient pharma supply chains built in Senegal and Nigeria through digital transformation	2.1.1 Number of technical assistance programmes to support functional Artificial Intelligence and machine learning drug discovery centres, technology transfer to local manufacturers, etc	2.1.1 0 (2023)	2.1.1 3 (2028)	2.1.1	

Output 2 **relating to Outcome 2**	2.2 The supply chain/logistics in Rwanda and Nigeria with a focus on quality assurance is strengthened	2.2.1 Number of ISO-certified Rwanda Medical Supply Ltd 2.2.2 Number of national EPCIS system integrated in Rwanda Medical Supply Ltd 2.2.3 How many projects to harness entire value chain of Natural resources supported including fill and finish manufacturing	2.2.1 0 2.2.2 0 2.2.3 0 (2023)	2.2.1 1 2.2.2 1 2.2.3 5 (2028)	2.2.1 Progress report 2.2.2 Progress report 2.2.3 Project implementation reports	
Output 3 **relating to Outcome 2**	2.3 Provide innovative access to finance and guarantees for nascent and established enterprises in South - Africa along the pharma value chain.	2.3.1.Number of biotech/pharma companies in South Africa that received financial support to sustain and expand business and product diversification	2.3.1 0	2.3.1 tbc	2.3.1. Project implementation reports Business register data	
Output 1 **relating to Outcome 3**	3.1 The capacities of the Regulatory Agency as a regional center of excellence have been enhanced in Ghana and South Africa	3.1.1 Enhanced capacity of the FDA as a regional centre of excellence. in Ghana. 3.1.2. Number of additional paper based processes of SAHPRA optimised through digitalisation in South Africa 3.1.3. Number of additional SAHPRA staff members that completed strategic training related to the vaccine manufacturing and pharma sector in South Africa and the use of efficient digital work processes supported by the project	3.1.1 0(2023) 3.1.2. tbc 3.1.3. 0(2023)	3.1 1 (2025) 3.1.2. tbc 3.1.3. tbc	3.1.1 Progress report 3.1.2. GIZ SAVAX progress reports 3.1.3. Progress reports	3.1.1 Commitment on the part of the FDA and Government sustained commitment to the process.
Output 2 **relating to Outcome 3**	3.2 Strengthen the technical capacity of the Egyptian Drug Authority to become WHO Listed Authority for Vaccines and Medicines.	3.2.1 EDA successfully assessed by WHO as maturity level 4 for medicines and vaccines.	3.2.1 EDA recognized as maturity level 3 by WHO	3.2.1 WHO assessed EDA on maturity level 4	3.2.1 WHO announcements	3.2.1 WHO to assess EDA during the project timeline.

Output 3 **relating to Outcome 3**	3.3 The structures and processes for lot release of vaccines and biologics in Ghana and Rwanda have been enhanced.	3.3.1 Lot release of vaccines and biologics enhanced in Ghana and Rwanda	3.3.1 0	3.3.1 5	3.3.1 Progress reports	3.3.1 Systems in place to facilitate lot release of vaccines and biologics.
Output 4 **relating to Outcome 3**	3.4 Support and Strengthen FDA Ghana's capacity as a Centre for Regional Excellence in Africa.	3.4.1 No of regulators and FDA staff capacity that have been enhanced.	3.4.1 80 regulators and 28 FDA staff (2023)	3.4.1 160 Regulators and 90 FDA staff (2027)	3.4.1 Project Progress reports	3.4.1 Commitment on the part of FDA and project implementation as scheduled.
Output 1 relating to Outcome 4	4.1 Partnerships for tech transfer according to the WHO guidelines on technology transfer in pharmaceutical manufacturing of WHO including support for licensing, and intellectual property have been strengthened.	4.1 Number of international networking and exchange events hosted or participated in by Ghanaian vaccine experts.	4.1.1 0	4.1.1 10 (2027)	4.1.1 Progress report	4.1.1 Project activities implemented as planned
Output 1 **relating to Outcome 5**	5.1 Improve the technical capacity of South African actors to conduct market analyses and design market-shaping measures for vaccines produced in South Africa.	5.1.1. South African actors have presented a study on the benefits of local production of vaccines and pharma products 5.1.2. One business case for local vaccine procurement has been approved by an interministerial and multi stakeholder group	5.1.1. 0 (2023) 5.1.2 0 (2023)	5.1.1. tbc 5.1.2 1 (end of project)	5.1.1. Progress report GIZ SAVAX Project report 5.1.2. Progress report Press releases	

Output 2 **relating to Outcome 5**	5.2 Strategic planning of the industrial development of Vaccines and Biologicals, including domestic production and export in Egypt and Nigeria strengthened.	5.2.1 Adoption of national strategy on domestic production and exports of vaccines and biological 5.2.2 Number of local manufacturers supported to meet international quality standards and regulatory requirements	5.2.1 0 5.2.2. 0 (2023)	5.2.1 1 5.2.2 5 (2028)	5.2.1 Government announcement 5.2.2 Project and government records	All public and private stakeholders will be engaged to develop a sectorial industrial strategy on vaccines and biologicals

4 IMPLEMENTATION ARRANGEMENTS

4.1 Financing Agreement by partner country(ies)

In order to implement this action, it is envisaged to conclude financing agreements with the partner countries Senegal, Rwanda, Ghana, Nigeria and Egypt.

It is envisaged that no financing agreement will be concluded with South Africa.

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 the entry into force of the financing agreements[21]

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 the adoption of the Financing decision.[22]

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[23].

Individual contracts for country level activities under this special measure will be managed by the EU Delegations in the respective countries.

4.3.1 **Direct Management (Grants)**

Grants: (direct management) 4.3.1

NIGERIA

a) **Purpose of the grant(s)**
The grant will contribute to achieving objectives 1, 2 and 5 of this Action.
Under S.O.1, support the enabling environment for local pharmaceutical and health technologies production through research and developing skills (higher education and vocational training); S.O.2, support industrial development through supply chain management including digitalisation and S.O.5 support fair pricing, market shaping and demand generation activities.

b) **Type of applicants targeted**

[21] Applicable to Senegal, South Africa, Rwanda and Ghana for which it is envisaged to conclude Financing agreements with partner countries
[22] Applicable to Nigeria and Egypt for which it is not envisaged to conclude Financing agreements with partner countries
[23] 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.

Non-profit organisation(s) with a sound level of technical competence, experience and expertise in the specialised field of production of quality medical products such as human medicines, vaccines, blood products, etc, development of human capacities in higher education training for the pharmaceutical/medical sector in Nigeria.

Public bodies mandated to enhance the development and commercialisation of pharmaceutical raw materials, drugs and biological products including vaccines from Nigeria's indigenous natural resources, as well as engage in activities relating to capacity building, policy making, data collation, drug distribution and the development of contextual partnerships that can expedite access to healthcare.

Public bodies mandated to establish institutional arrangements, supervise and coordinate research, training and related activities as well as can receive and manage funding support from partners, private or other stakeholders.

c) **Justification of a direct grant**

Under the responsibility of the Commission's authorising officer responsible, the recourse to an award of a grant without a call for proposals is justified because the entities should have exclusive competence in the field of the activity. In line with Article 195, f) of the Financial Regulation, this action requires public bodies and non-profit organisations to have a high level of technical competence and high degree of specialisation while being locally reputable. In light of this, the selectin criteria which will ensure the compliance with the principles of art. 195 (f) for a direct award of grants are detailed below:

- Non-profit organisation/s legally established in Nigeria with a sound level of technical competence, experience and expertise in providing specialised training programmes for students and industry staff to advance their careers in Nigeria. Public bodies semi-autonomous / independent government institutions.
- Public bodies with a government mandate as a National Research Institute responsible for the development and commercialisation of pharmaceutical raw materials, drugs and biological products including vaccines from Nigeria's indigenous natural resources.
- Public bodies having the government mandate to directly receive EU funds / grants.

The part of the action under the budgetary envelope reserved for grants may, partially or totally and including where an entity is designated for receiving a grant without a call for proposals, be implemented in indirect management with an entity, which will be selected by the Commission's services using the following criteria:

- relevant expertise and experience in relation to the nature of the intervention;
- operational capacity in Nigeria;
- on-going engagement in the sector and on-going policy dialogue with the Government of Nigeria.

GHANA

(**a) Purpose of the grant(s)**
The grant will contribute to achieving specific objective 1 and 3 of this Action.

Under S.O. 1 Support the enabling environment for local pharmaceutical and health technologies production through research and developing skills (higher education and vocational training (TVET) and S.0 3 strengthen the regulatory environment in countries in view of complementing regional level regulatory support.

(b) Type of applicants targeted
Non-profit organisation/s with a sound level of technical competence, experience and expertise in the specialised field of production of human medicines and vaccines, development of human capacities in higher

education training for the pharmaceutical sector in Ghana.

Public bodies mandated to ensure the safety, quality and efficacy of human and veterinary drugs, food, biological products, cosmetics, medical devices, household chemical substances and clinical trials and the control of tobacco products through the enforcement of relevant standards to protect public health with *de jure* monopoly in their domains and with a sound expertise in the regulation of food and medical products.

Public bodies mandated to establish institutional arrangements, supervise and coordinate research and development and manufacture of vaccines and sera with *de jure* monopoly in their domains and with a sound expertise in the coordination and supervision of research, development and manufacturing of vaccines and sera for related matters.

(c) Justification of a direct grant

Under the responsibility of the Commission's authorising officer responsible, the recourse to an award of a grant without a call for proposals is justified because the entities should have exclusive competence in the field of the activity. In line with Article 195, f) of the Financial Regulation, this action requires public bodies and non-profit organisations to have a high level of technical competence and high degree of specialisation while being locally reputable. In light of this, the selectin criteria which will ensure the compliance with the principles of art. 195 (f) for a direct award of grants are detailed below:

- Non-profit organisation/s with a sound level of technical competence, experience and expertise in providing biomanufacturing training programs for students and industry staff to advance their careers in Ghana.
- Public bodies semi-autonomous / independent government institutions.
- Public bodies with a government mandate as National Regulatory Body responsible for the regulation of food, drugs, food supplements, medicines as well as the conduct of clinical trials protocols.
- Public bodies with a government mandate to establish institutional arrangements, supervise and coordinate research and development and manufacture of vaccines in Ghana.
- Public bodies having the mandate to directly receive EU funds / grants.

The public bodies need to be legally granted the de jure monopoly to carry out the activities described in the action, notably coordination and supervision of research, development and manufacturing of vaccines and sera for related matters and responsible for the regulation of food, drugs, food supplements, medicines as well as the conduct of clinical trials protocols.

The part of the action under the budgetary envelope reserved for grants may, partially or totally and including where an entity is designated for receiving a grant without a call for proposals, be implemented in indirect management with an entity, which will be selected by the Commission's services using the following criteria:

- relevant expertise and experience in relation to the nature of the intervention;
- operational capacity in Ghana;
- on-going engagement in the sector and on-going policy dialogue with the Government of Ghana.

SOUTH AFRICA

(**a) Purpose of the grant(s)**

The grant will contribute to achieving the specific objectives of 1 and 3 of the action.

Under S.O. 1 Support the enabling environment for local pharmaceutical and health technologies production through research and developing skills (higher education and vocational training (TVET) and S.O 3 strengthen the regulatory environment in countries in view of complementing regional level regulatory support.

The grant may also support activities under specific objective 2 Support industrial development, supply chain management and integrity, including digitalisation.

(b) Type of applicants targeted
European academia and research institutes that have strong reputation in biomedical, clinical and public health research, advanced education, as well as capacity-building in developing countries that can demonstrate established partnerships with South African counterparts.

The entities shall demonstrate experience in managing international cooperation programmes funded in a Team Europe approach in the region of Sub-Saharan Africa.

(c) Justification of a direct grant

Under the responsibility of the Commission's authorising officer responsible, the recourse to an award of a grant without a call for proposals is justified because the entities should have exclusive competence in the field of the activity. In line with Article 195, f) of the Financial Regulation, this action requires public bodies and non-profit organisations to have a high level of technical competence and high degree of specialisation while being locally reputable. In light of this, the selectin criteria which will ensure the compliance with the principles of art. 195 (f) for a direct award of grants are detailed below:

- Public utility organisation/s legally established in the EU with a sound level of technical competence, experience and expertise in biomedical, clinical and public health research, advanced education as well as capacity building in developing countries that can demonstrate established partnerships with counterparts in South Africa.
- Public bodies having the mandate and experience to directly receive and manage EU funds / grants.

The part of the action under the budgetary envelope reserved for grants may, partially or totally and including where an entity is designated for receiving a grant without a call for proposals, be implemented in indirect management with an entity, which will be selected by the Commission's services using the following criteria:

- relevant expertise and experience in relation to the nature of the intervention,
- operational capacity in South Africa,
- on-going engagement in the sector and on-going policy dialogue with the Government of South Africa.

EGYPT

(**a) Purpose of the grant(s)**

The grant (Twinning) will contribute to achieving specific objective 3 of this action.

Under S.O. 3 strengthen the regulatory environment in countries in view of complementing regional level regulatory support

(b) Type of applicants targeted

EU Member States public bodies mandated to ensure the safety, quality and efficacy of human and veterinary drugs, biological products, cosmetics, medical devices and clinical trials through the enforcement of relevant standards to protect public health with *de jure* monopoly in their domains and with a sound expertise in the regulation of drugs and medical products.

(c) Justification of a direct grant

Under the responsibility of the Commission's authorising officer responsible, the recourse to an award of a grant without a call for proposals is justified because the entities should have exclusive competence in the field of the activity. In line with Article 195, f) of the Financial Regulation, this action requires public bodies and

non-profit organisations to have a high level of technical competence and high degree of specialisation while being locally reputable. In light of this, the selectin criteria which will ensure the compliance with the principles of art. 195 (f) for a direct award of grants are detailed below:

- Public bodies semi-autonomous / independent government institutions.
- Public bodies with a government mandate as a National Regulatory Body responsible for the regulation of drugs, medicines as well as the conduct of clinical trials protocols.
- Public bodies having the government mandate to directly receive EU funds / grants.

The public bodies need to be legally granted the de jure monopoly to carry out the activities described in the action, notably coordination and supervision of research, development and manufacturing of vaccines and sera for related matters and responsible for the regulation of drugs, medicines as well as the conduct of clinical trials protocols.

The part of the action under the budgetary envelope reserved for grants may, partially or totally and including where an entity is designated for receiving a grant without a call for proposals, be implemented in indirect management with an entity, which will be selected by the Commission's services using the following criteria:

- relevant expertise and experience in relation to the nature of the intervention,
- operational capacity in Egypt,
- on-going engagement in the sector and on-going policy dialogue with the Government of Egypt.

4.3.2 **Direct Management (Procurement)**

For Ghana, procurement through service contracts to provide technical assistance support for related activities under the Action specifically under S.O. 1 Support the enabling environment for local pharmaceutical and health technologies production through research and developing skills (higher education and vocational training (TVET). The other areas for technical assistance support may include activities under S.O. 3 Strengthen the regulatory environment in countries in view of complementing regional level regulatory support. Technical assistance support will also cover auxiliary services to support an effective implementation of the Action.

For Nigeria, procurement through service contracts to provide relevant technical assistance during the execution of the Action to support the implementation of activities under S.O.1, S.O.2 and S.O. 5 including analysis, studies, etc.

For Egypt, procurement through service contract to support the implementation of S.O. 5 Support demand for locally produced goods including forecasting, **procurement** and distribution of health products.

4.3.3 **Indirect Management with an entrusted entity**

SENEGAL

This Action may be implemented in indirect management with pillar assessed entrusted entities, leveraging on existing mechanisms (public policy financing) as well as on the pool of expertise that can be brought by the EU, Member States and European financing institutions following a Team Europe approach. The implementation through indirect management mode could be channeled through: (i) project approach bringing technical expertise and (ii) a possible second phase of the public policy financing operation currently jointly conducted with DE (KfW) and FR (AFD).

The implementing entities will be selected by the Commission's service using the following criteria:

- Under the "project approach" (contributing to achieving Specific Objectives 1 and 2): indirect management with pillar assessed entities: European partners within the network of EU Member States and corresponding agencies, who (i) have a specific expertise in the sector and (ii) can bring a clear

added value to contribute to the objectives of the action;

- Under the “"public policy financing approach” (contributing to achieving Specific Objectives 1, 2 and 3): indirect management with a pillar assessed entity also supporting the national plan for the pharmaceutical industry through a public policy financing instrument. An alternative is described in section 4.3.4.

The implementation by these entities entails activities that will contribute to Specific Objective 1: Support the enabling environment for local pharmaceutical and health technologies production through research and developing skills (higher education and vocational training (TVET)), Specific Objective 2: support industrial development, supply chain management and integrity, including digitalisation and Specific Objective 3: strengthen the regulatory environment in countries in view of complementing regional level regulatory support.

RWANDA

The Action may be implemented in indirect management with entrusted entities. The action will leverage existing partnerships and specific expertise of Team Europe.

The implementing entities may be selected by the Commission’s service using the following criteria:

- Experience in implementing activities that contribute to similar objectives than that of the Action.

The implementation by this entity entails implementation of part of the Action under Specific Objective 1: Support the enabling environment for local pharmaceutical and health technologies production through Research & Development and developing skills (managerial abilities, higher education and vocational training (TVET) and under Specific Objective 2: Support industrial development, supply chain management and integrity, including digitalisation.

GHANA

A part of this action may be implemented in indirect management with entrusted entities, which will be selected by the Commission’s services using the following criteria:

1. Sound experience with support to actions related to S.O. 1, S.O. 3 and S.O. 4 in Africa and specifically Ghana;
2. Experience supporting institutions in the areas of local pharmaceutical and health technologies production through research and skills development and promotion of technology transfers, licensing and intellectual property management);
3. Operational capacity, value addition transparency and absence of conflict of interest;
4. Capacity to mobilise funds to possibly co-finance the action;
5. Experience in pharma and other health industries.

The implementation by these entities may entail implementation of a part of the Action under S.O. 1 Support the enabling environment for local pharmaceutical and health technologies production through research and developing skills (higher education and vocational training (TVET) and S.O. 3 Strengthen the regulatory environment in countries in view of complementing regional level regulatory support and S.O. 4 Promote technology transfers, licensing and intellectual property management.

SOUTH AFRICA

Part of this action may be implemented in indirect management with entrusted entities, which will be selected by the Commission’s services using the following criteria:

1. Experience in implementing or is currently implementing activities that contributes to the objectives of the Action;
2. Demonstrating sufficient operational capacity, operational, logistical, management, financial and good governance capacities;
3. Having technical expertise in the niche area of the action as well as ongoing policy dialogue with

Government of South Africa.

The implementation by the entity(ies) entails activities that will contribute to Specific Objective 1: Support the enabling environment for local pharmaceutical and health technologies production through research and developing skills (higher education and vocational training (TVET)) and Specific Objective 3: strengthen the regulatory environment in countries in view of complementing regional level regulatory support and Specific Objective 5: Support demand and supply of locally produced goods including forecasting, procurement and distribution of health products in view of complementing regional level efforts. It could also contribute to Specific Objective 2: support industrial development, supply chain management and integrity, including digitalisation. An alternative is described in section 4.3.4 for the implementation of Specific Objectives 1, 2 and 5.

NIGERIA

Part of the Action may be implemented in indirect management with entrusted entities. The Action will leverage existing partnerships and specific expertise of Team Europe. The implementing entities will be selected by the Commission's service using the following criteria:

- Experience in implementing or is currently implementing activities that contribute to the objectives S.O. 1, S.O. 2 and S.O. 5 of the Action
- Demonstrating sufficient operational, logistical, management, financial and good governance capacities
- Having technical expertise in the niche area of the action

Fall back option will be direct management through grant to a research organisation(s) or other technically competent entity(ies).

EGYPT

The Action may be implemented in indirect management and managed by the EUD to Egypt.

Indirect Management with an entrusted entity:

A part of this action may be implemented in indirect management with a pillar assessed entity, which will be selected by the Commission's services using the following criteria:

- Relevant expertise and experience in relation to the nature of the intervention,
- Operational capacity in Egypt,
- On-going engagement in the sector and on-going policy dialogue with the Government of Egypt.

The implementation by the entities entail activities that will contribute to Specific Objective 1: Support the enabling environment for local pharmaceutical and health technologies production through research and developing skills (higher education and vocational training (TVET).

4.3.4 **Contribution to the African Investment Platform**[24]

In Senegal, part of this contribution may be implemented under indirect management with the entities, called Lead Finance Institutions, identified in the appendix to this Action Document.

As an alternative of the modality described in section 4.3.3, the contribution under the "public policy financing approach" (contributing to achieving Specific Objectives 1, 2 and 3) may be blended with a financing provided by a Lead Finance Institution supporting the national plan for the pharmaceutical industry through a public policy loan. The synergies and complementarity with TEI MAV+ Blending platform will be foreseen.

In South Africa, part of this contribution may be implemented under indirect management with the entities,

[24] Regulation (EU) 2021/947 of the European Parliament and of the Council of 9 June 2021 establishing the Neighbourhood, Development and International Cooperation Instrument (europa.eu)

called Lead Finance Institutions, identified in the appendix to this Action Document.

As an alternative of the modality described in section 4.3.3, the contributions to Specific Objectives 1, 2 and 5 may be blended with a financing provided by a Lead Finance Institution. The synergies and complementarity with TEI MAV+ Blending platform will be foreseen.

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

EGYPT

If the implementation modality of the twinning described under 4.3.1 cannot be implemented due to circumstances outside the Commission control, an alternative option is to be implemented through indirect management with an entrusted entity, which will be selected by the Commission's services using the following criteria:

- Relevant expertise and experience in relation to the nature of the intervention,
- Operational capacity in Egypt,
- On-going engagement in the sector and on-going policy dialogue with the Government of Egypt.

The implementation by the entity(ies) entails activities that will contribute to Specific Objective 3: strengthen the regulatory environment in countries in view of complementing regional level regulatory support.

NIGERIA

If the implementation modality of indirect management with an entrusted entity prove impossible for reasons outside the Commission's control, then the activities under this pillar supporting specific objectives 1, 2 and 5 may be implemented under direct management as follows:

1. Procurement (direct management): Part of the Action supporting Specific Objectives 1, 2 and 5 may be implemented by a service contract/technical assistance. The purpose of the procurement procedure would be to provide technical assistance to the relevant stakeholders in terms of analysis, studies, training, etc.

2. Grants (direct management): Part of the Action supporting Specific Objectives 1, 2 and 5 may be implemented by grants to technically competent NGOs and or Public bodies with requisite mandate for local manufacture of health products. The purpose of the grants would be to provide seed capital to support enabling environment for local production of health products through research and skills development, supply chain management, market shaping and demand generation activities.

   Criteria for grants in direct management:

   The call for proposals will mainly target NGOs and or national research organisation(s) or other technically competent entity(ies) with mandate for local manufacture of medical products, capacity to link academia, and industry and or capacity for commercialisation of locally manufactured products.

SOUTH AFRICA

If the implementation modality of indirect management with an entrusted entity prove impossible for reasons outside of the Commission's control, then the activities under this pillar supporting specific objective 2 may be implemented under direct management as follows:

1. Procurement (direct management): Part of the Action supporting Specific Objectives 1, 2,3 and 5 may be implemented by a service contract/technical assistance. The purpose of the procurement procedure would be to provide technical assistance to the relevant stakeholders in terms of pharma value chain

strengthening.
2. Grants (direct management): Part of the Action supporting Special Objective 2. may be implemented by grants to start up or spin off companies. The purpose of the grants would be to provide seed capital, short term trainings, capacity building, tailor-made training courses and consultancy services to start up or consolidate presence in pharma value chain.

Criteria for grants in direct management:

The call for proposals will mainly target nascent companies or those that want to differentiate products or business models in the pharma value chain. Applicants are either sole applicants (should be then legal entities established in South Africa) or consortia of applicants (comprising at least one legal entity established in South Africa).

GHANA

If the implementation modality of indirect management with an entrusted entity prove impossible for reasons outside of the Commission's control, then the activities under this pillar supporting Specific Objective 1 may be implemented under direct management as follows:

1. Procurement (direct management): Part of the Action supporting Specific Objectives 1, 3 and 4 may be implemented by a service contract/technical assistance. The purpose of the procurement procedure would be to provide technical assistance to the relevant stakeholders in terms of pharma value chain strengthening.
2. Grants (direct management): Part of the Action supporting Special Objective 1 and 3. The purpose of the grants would be to provide, capacity building, tailor-made training courses,consultancy services and other related support areas to consolidate presence in pharma value chain.

Criteria for grants in direct management:

- Non-profit organisation/s with a sound level of technical competence, experience and expertise in providing biomanufacturing training programs for students and industry staff to advance their careers.
- Public bodies legally granted a de jure monopoly to carry out the activities described in the action, notably coordination and supervision of research, development and manufacturing of vaccines and sera for related matters;
- Public bodies responsible for the regulation of food, drugs, food supplements, medicines as well as the conduct of clinical trials protocols.

4.4 Scope of geographical eligibility for procurement and grants

The geographical eligibility in terms of place of establishment for participating in procurement and grant award procedures and in terms of origin of supplies purchased as established in the basic act and set out in the relevant contractual documents shall apply subject to the following provisions.

The Commission's authorising officer responsible may extend the geographical eligibility on the basis of urgency or of unavailability of services in the markets of the countries or territories concerned, or in other duly substantiated cases where application of the eligibility rules would make the realisation of this action impossible or exceedingly difficult (Article 28(10) NDICI-Global Europe Regulation).

4.5 Indicative Budget

BUDGET/ COUNTRY	**Implementation modalities**	**EU Contribution (EUR)**	**Third-party contribution**

South Africa		**16,000,000**	
	Grants – total envelope under section 4.3.1	2,000,0000	
	Indirect management with entrusted entities - cf. section 4.3.3	7,000,0000	
	Indirect management with Lead Finance Institutions identified in the appendix to this Action Document - cf. section 4.3.4	7,000,0000	
Egypt		**3,000,000**	
	Grants – total envelope under section 4.3.1	1,500,000	
	Procurement – total envelope under section 4.3.2	500,000	
	Indirect management with entrusted entities - cf. section 4.3.3	1,000,000	
Senegal		**25,000,000**	
	Indirect management with entrusted entities – cf. Section 4.3.3 (for part of the action and as an alternative only, indirect management with Lead Finance Institutions might be foreseen in line with par. 4.3.4)	25000000	TBC
Rwanda		**40,000,000**	
	Indirect management with entrusted entities – cf. section 4.3.3	40,000,000	TBC
Ghana		**32,000,000**	
	Grants – total envelope under section 4.3. 1	7 000 000	TBC
	Procurement – total envelope under section 4.3.2	1 600 000	
	Indirect management with entrusted entity – cf. Section 4.3.3	23 000 000	TBC
	Evaluation and Audits – cf. section 5.3	400 000	
Nigeria		**18,000,000**	
	Grants – total envelope under section 4.3.1	10 000 000	TBC
	Procurement – total envelope under section 4.3.2	2 000 000	
	Indirect management with entrusted entity – cf. Section 4.3.3	5 500 000	TBC
	Evaluation and Audits – cf. section 5.3	500 000	

4.6 Organisational Set-up and Responsibilities

This Action contributes to the health-relevant industries development, market shaping, regulatory strengthening, technology transfer and R&D, higher education and skills work streams in Africa under the Team Europe Initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (TEI MAV+) for Sub-Saharan Africa, expanded through the present action to North Africa in collaboration with DG

NEAR.

The implementation arrangements already agreed and adopted in the framework of the existing interventions under MAV+, will be maintained under the current Action.

Thus, the MAV+ steering structures are EC steered and will ensure overall guidance, coordination and monitoring of the actions in close collaboration with the EUDs. The structures will also steer future actions under the MAV+ and under the special measure (2024) and ensure proper coordination and synergies with the present Action.

In the framework of the new interventions funded under the present Action, based on the AD, each EU Delegation/ Commission services will ensure a proper implementation of the interventions according to the objectives, conclude and manage the relevant contracts and monitor progress.

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 the overarching structure of the MAV+ steering comprises:

1. A High-Level Steering that provides policy and overall strategic guidance of the MAV+ and other health programmes. 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) are co-chaired by the the Commission (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) provides operational guidance, define milestones and coordinate the Team Europe 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 includes 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.

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. 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 Enabel 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. Where a financing agreement is planned, the exception from D+3 shall apply for evaluations. In such case, the evaluations should be implemented by way of procurement beyond the operational procurement envisaged in the relevant section. The overall budget allocated for Evaluation together with Audit are included in section 4.5.

Evaluation services may be contracted. Where no financing agreement will be concluded, 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 - Eligible Lead Finance Institutions

Final eligibility will have to be approved by the African Operational Board and contain only pilar assessed entities for financial instruments at the time of contracting.

ADB	Asian Development Bank
AFD	Agence Française de Développement
AfDB	African Development Bank
BDB	Bulgarian Development Bank
BGK	Bank Gospodarstwa Krajowego
BIO	Belgian Investment Company for Developing Countries (BIO N.V./S.A.), Belgium
BOAD	Banque Ouest Africaine de Developpement
BPF	Banco Portgues de Formento
CDC	Caisse des dépôts et consignations
CDP	Cassa depositi e prestiti S.p.A., Italy
CEB	Council of Europe Development Bank
CMZRB	Czech-Moravian Guarantee and Development Bank
COFIDES	Compañía Española de Financiación del Desarrollo, Spain
DBSA	Development Bank of Southern Africa, South Africa
DEG	Deutsche Investitions- und Entwicklungsgesellschaft mbH, Germany
EBRD	European Bank for reconstruction and development
EDFI MC	European Development Finance Institutions Management Company
EIB	European Investment Bank
EIF	European Investment Fund
EXIMBANKA SR	Export-Import Bank of the Slovak Republic
FINNFUND	Finnish Fund for Industrial Cooperation Ltd - Teollisen yhteistyön rahasto Oy
FMO	Nederlandse Financierings-Maatschappij voor Ontwikkelingslanden, Netherlands
ICF	Institut Català de Finances
IFU	Investment Fund for Developing Countries
KfW	Kreditanstalt fur Wiederaufbau, Germany
NIB	Nordic Investment Bank
OeEB	Development Bank of Austria
PROPARCO	Groupe Agence Française de Développement, France
SBCI	The Strategic Banking Corporation of Ireland

SID	Slovenska izvozna in razvojna banka, d.d
Swedfund	Swedfund International AB
WBG	World Bank Group (IBRD, IDA, IFC, MIGA, ICSID)
WFP	World Food Program

Appendix 2 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	
Group of actions level (i.e., top-up cases, different phases of a single programme)		
x	Group of actions	Actions reference (CRIS#/OPSYS#): Present action: ACT-62262 (Senegal) ACT-62266 (Egypt) ACT-62268 (South Africa) ACT-62269 (Rwanda) ACT-62270 (Ghana) ACT-62271 (Nigeria) Previous actions: ACT-62011 (MAV+ III) ACT-61342 (MAV+ II) ACT- ACT-61139 (MAV+ I)
Contract level		
☐	Single Contract 1	
☐	Single Contract 2	
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	