EN

THIS ACTION IS FUNDED BY THE EUROPEAN UNION

ANNEX 1

to the Commission Implementing Decision on the financing of the multiannual action plan in favour of Sub-Saharan Africa for 2022-2026 Part 2

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

MULTIANNUAL PROGRAMME
This document constitutes the multiannual work programme within the meaning of Article 110(2) of the Financial Regulation, within the meaning of Article 23 of the NDICI-Global Europe Regulation.

1 SYNOPSIS

1.1 Action Summary Table

1. Title **CRIS/OPSYS business reference** **Basic Act**	Regional dimension and management of the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa (part II) OPSYSACT-61342 Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe)
2. Team Europe Initiative	Yes, it supports the regulatory work stream of the Team Europe initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa.
3. Zone benefiting from the action	The action shall be carried out in Africa.
4. Programming document	Multi-Annual Indicative Programme for Sub-Saharan Africa 2021-2027
5. Link with relevant MIP(s) objectives / expected results	Priority Area 1: Human Development Specific Objective 1 (Health): Strengthen the African health security architecture, pharmaceutical systems and public health capacity, contributing to stronger, more resilient health systems and improved health outcomes. Result 1.2: Pharmaceutical systems in Africa and the regional manufacturing capacity for vaccines and other medical products and technologies are strengthened to increase quality, safety and equitable access.
PRIORITY AREAS AND SECTOR INFORMATION	
6. Priority Area(s), sectors	Human development, health, 120
7. Sustainable Development Goals (SDGs)	Main SDG: SDG 3 (health)

	Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. Other significant SDGs: SDG 5 (gender equality) SDG 8 (economic growth) SDG 9 (industry and innovation) SDG 10 (educe inequality within and among countries) SDG 16 (good governance) and SDG 17 (partnerships).			
8 a) DAC code(s)	DAC code 1 – 12110, Health policy and administrative management 70% DAC code 2 – 12181, Medical education/training – 10% DAC code 3 – 12264, COVID-19 control – 10% DAC code 4 – 32168, Pharmaceutical production – 10%			
8 b) Main Delivery Channel	European Union Institutions – 42000 Public entity - 12000			
9. Targets	☐Migration ☐ Climate ☒Social inclusion and Human Development ☒Gender ☐ Biodiversity ☐ Education ☐ Human Rights, Democracy and Governance			
10. Markers (from DAC form)	**General policy objective**	**Not targeted**	**Significant objective**	**Principal objective**
	Participation development/good governance	☒	☐	☐
	Aid to environment	☒	☐	☐
	Gender equality and women's and girl's empowerment	☐	☒	☐
	Trade development	☐	☒	☐
	Reproductive, maternal, new-born and child health	☐	☒	☐
	Disaster Risk Reduction	☐	☒	☐
	Inclusion of persons with Disabilities	☐	☒	☐
	Nutrition	☒	☐	☐
	RIO Convention markers	**Not targeted**	**Significant objective**	**Principal objective**
	Biological diversity	☒	☐	☐
	Combat desertification	☒	☐	☐
	Climate change mitigation	☒	☐	☐

	Climate change adaptation	☒	☐	☐
11. Internal markers and Tags:	**Policy objectives**	**Not targeted**	**Significant objective**	**Principal objective**
	Digitalisation	☐	☒	☐
	digital connectivity digital governance digital entrepreneurship digital skills/literacy digital services	YES ☐ ☒ ☐ ☒ ☐	NO ☐ ☐ ☐ ☐ ☒	
	Connectivity	☒	☐	☐
	digital connectivity energy transport health education and research	YES ☐ ☐ ☐ ☐	NO ☐ ☐ ☐ ☐	
	Migration (methodology for tagging under development)	☒	☐	☐
	Reduction of Inequalities (methodology for marker and tagging under development)	☐	☒	☐
	Covid-19	☐	☒	☐
BUDGET INFORMATION				
12. Amounts concerned	Budget lines Total estimated cost for 2022: EUR 20 000 000 **Total amount of EU budget contribution for 2022: EUR 20 000 000** o 14.020120-C1-INTPA (West Africa): EUR 7 000 000 o 14.020121-C2-INTPA (East and Central Africa): EUR 7 000 000 o 14.020122-C1-INTPA (Southern Africa/ Indian Ocean): EUR 6 000 000 The 'context' section below provides detailed information on related projects and Team Europe support to this specific MAV+ regulatory work stream (BE, FR, DE)			
MANAGEMENT AND IMPLEMENTATION				
13. Type of financing	**Direct management** through grants. **Indirect management** with the European Medicines Agency (EMA)			

1.2 Summary of the Action

The Action will contribute to the Team Europe initiative on manufacturing and access to vaccines, medicines and health technologies (**MAV+**) by supporting the **development of regulatory systems on the African continent and the establishment of the African Medicines Agency (AMA)**. It will benefit from the expertise

and experience of the **European medicines regulatory network,** including the **European Medicines Agency (EMA).**

The multiannual indicative programme (MIP) for Sub-Saharan Africa 2021-2027[1] includes human development as its first priority area. Within this priority, the specific objective 1 is strengthening "the African health security architecture, pharmaceutical systems and public health capacity, contributing to stronger health systems and improved health outcomes". More specifically, result 1.2 refers to **reinforcing "the African pharmaceutical systems and the regional manufacturing capacity for vaccines and other medical products and technologies**" to increase "quality, safe and equitable **access**". This result is of particular relevance as the consequences of COVID-19 persist. This result will contribute to lay the foundation for an innovative pharmaceutical and health care industrial sector in Africa integrated into the global health architecture, and it will underpin the health and well-being of future generations. Supporting access to essential health products and technologies represents an opportunity to target several development objectives and geo-political priorities shared by both the EU and the African Union (AU), stimulate growth and decent jobs, facilitate trade, diversify global value chains, engage with the private sector, and reinforce our health, scientific and diplomatic ties with partner countries while advancing universal health coverage (UHC) and human development. Nevertheless, the development of local production needs to go in parallel to regulatory strengthening to secure access by users to quality medical products.

MAV+ offers a comprehensive, **360-degree approach** (details in section 2.2) that takes into account three dimensions: supply and demand side, and the enabling environment. It revolves around **6 work streams**: 1) industrial development, supply chains and private sector, 2) market shaping, demand and trade facilitation, 3) regulatory strengthening, 4) technology transfer and intellectual property management, 5) access to finance, 6) R&D, higher education and skills. It encompasses national and regional level interventions.

This Action refers to the **regulatory strengthening work stream** and represents the second **regional** action under MAV+. The intervention logic of the first regional Action (RIP AAP 2021) included four specific objectives (SO) regarding 1) the advancement of regulatory convergence, harmonisation, and use of reliance mechanisms between regulatory authorities, 2) technology transfer and innovation for local production, 3) demand consolidation and strategic purchasing, and 4) enhancing coordination and management. Regarding SO 1, contracts with implementers, World Health Organization (WHO) and the African Union Development Agency (AUDA-NEPAD), are currently under finalization. The latter is leading the African Medicine Regulatory Harmonisation (AMRH) project and the establishment of the **African Medicines Agency (AMA)** –details in section 2.1. The AAP 2022 represents a second logical step to advance this agenda. The budget for this action is of EUR 20 million. In order to cover the remaining gaps in the regulatory domain, the intervention logic of this second regional Action focuses on two specific objectives –further detailed in **section 3**–:

1. Strengthen medicines and healthcare products regulatory systems in Africa through regulatory harmonisation, convergence and reliance mechanisms. 2. Enhance EU/EMA-AU/AMA cooperation, effective coordination and good governance of health products.

It recognises the political imperative of supporting vaccine manufacturing, and it seeks to differentiate the European Union from other partners in two ways. First, through establishing its credentials in support of the broader agenda on access to medicines, access to innovation and strengthening systems. Secondly, through helping African actors and solutions deliver for Africa's challenges and with African partners.

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

1 C(2021) 9373 final COMMISSION IMPLEMENTING DECISION of 15.12.2021 adopting a multiannual indicative programme for Sub-Saharan Africa for the period 2021-2027

Gender is an important factor influencing caregiving as well as demand, access and use of health services and products including immunisation services for women, adolescent girls and children.

Consequently, the concerned DAC codes are related to health (12110, health policy and administrative management; 12181, medical education/training; 12264, COVID-19 control) and industry (32168, pharmaceutical production).

2 RATIONALE

2.1 Context

The entry into force of the **Treaty for the Establishment of the African Medicines Agency (AMA)**, on the 5th of November 2021, marks and important milestone and highlights the urgency of making its implementation successful. The AMA will be one of the critical actors to promote regional market integration in Africa for the pharmaceutical sector. By April 2022, 31 African countries backed in some form the AMA and 22 of them have completed its ratification and deposited the AMA treaty instrument to the AU secretariat (Algeria, Benin, Burkina Faso, Cameroon, Chad, Gabon, Guinea, Ghana, Mali, Mauritius, Morocco, Namibia, Niger, Rwanda, Saharawi, Senegal, Seychelles, Sierra Leone, Tunisia, Uganda, Zimbabwe and Egypt).

The European Commission took the initiative to convene the African Union Development Agency-NEPAD (AUDA-NEPAD) and donors (members of the Team Europe Initiative including Belgium, France, Germany and the Bill & Melinda Gates Foundation) before the AU-EU Summit to explore ways to effectively strengthen medicines regulators and improve health security. Consequently, the 15th of February 2022 it was announced[2] the collective mobilization of more than **100 million euro** over the next five years to support the recently established African Medicines Agency (AMA) and other African medicines regulatory initiatives at regional and national levels. This support to strengthening regulatory capacity will improve health security in Africa, including through the expansion of local manufacturing of quality, safe, efficacious, and affordable medicines, vaccines, and other health tools. The **total EC funding** combining regional and national initiatives **surpasses 50 million euro**, encompassing the 20 million of this regional Action.

The concrete Action presented in this document responds to this critical institutional development for Africa, and does it on the basis of the **unique expertise and regulatory model that the EU can offer**. No other regional example in the entire world is as functional and complete as the European model. Therefore, the AMA has an opportunity to fetch lessons learned from the European regulatory harmonisation and speed up its full establishment and operationalization. Location of AMA's headquarters will be in Rwanda.

This Action is an integral part of the Team Europe Initiative (TEI) on **Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+)**, to which the EU has pledged EUR 1 billion, announced by President von der Leyen at the Global Health Summit in May 2021. MAV+ is one of the **Global Gateway's** Flagships, and part of a set of regional **health TEIs in Africa**. A streamlined steer, management and coordination will allow for maximized synergies across all the health-related TEIs. For example, MAV+ outcomes benefit directly from resources under the TEI on digital health, and particularly from the digital tools (i.e. global trust repository) which are being implemented to improve health products traceability. Likewise, MAV+ will target regulatory needs for all essential health products, including SRHR commodities and priority assistive products. MAV+ is expected to benefit from a **High Level Policy Structure co-led by the European Commission (EC) and the African Union Commission (AUC)**.

MAV+ is aligned with the **Pharmaceutical Strategy for Europe**, complements the **EU4Health** programme and will contribute to the **new EU Global Health Strategy**. As part of the Pharmaceutical Strategy for Europe adopted in November 2020, a key pillar is ensuring a strong EU voice in the world, by promoting a high level of quality, efficacy, and safety standards. The EU regulatory system on pharmaceuticals is recognised as a well-developed reliable and mature system and could serve as a model for the establishment of the AMA.

The Action focuses on the specific **EC contribution** to this TEI's regulatory work stream and complements a previous regional action (EC decision from December 2021) that resulted in a 5 million euro direct grant to **AUDA-NEPAD** in support of the African Medicines Regulatory Harmonization initiative (AMRH) and the roadmap to

[2] AMA announcement https://ec.europa.eu/commission/presscorner/detail/en/IP_22_993

the AMA, and a 24,5 million grant to **WHO**, of which 11,5 million for regulatory strengthening. The corresponding contracts are being finalized, pending the signature of a simplified financing agreement with the AUC. However, existing funding has not been sufficient to activate the sharing of the scientific and technical expertise of the **European Medicines Agency** (EMA) amongst other technical partners. Likewise, the implementation of the **African Medicines** (AMA) Treaty will require additional resources once the host country is selected. The AMA will confront the complexity of coordinating national (national regulatory authorities, NRAs), regional (Regional Economic Communities –RECs-) and the continental regulatory systems. Hence all these needs justify the allocation of an additional amount of 20 million euro.

While AMA's configuration is taking shape, regulatory support from the EC is ongoing at **country level**. Regulatory strengthening interventions are already being implemented in favor of national regulatory authorities (NRAs) under the leadership of the EU Delegations to Rwanda and Ghana. In Rwanda, a total of 9,8 million euro have been made available by the EC. A contract has been signed with Enabel (with an EU contribution of 7 million) and 2 million will facilitate a twinning operation between the Rwanda Food and Drugs Authority (FDA) and a consortium of European experts and regulators led by Expertise France. Dialogue is ongoing around this theme in additional INTPA countries (Senegal, South Africa, Nigeria, Zambia, Botswana, Kenya, etc.) and NEAR countries (Egypt). Likewise, related EU-led **regional** initiatives are still active, such as the SIPS programme (Support towards the Industrialisation and the Productive Sectors) in the SADC region, and the Medisafe project against substandard and falsified medicinal products in East and Central Africa. All these initiatives will provide lessons to learn from and should be taken into account by the implementers of this action and other EU implementers active in this space.

Commission services, with DG INTPA in the lead and in coordination with DG RTD, GROW, SANTE, HERA, JRC or TRADE, designed MAV+ to supportthe AU-EU partnership in health. In this context, it is worth mentioning the support provided to regulatory enhancement, notably of clinical trials, through the European and Developing Countries Clinical Trials Partnership (EDCTP2), and a new 5 million call proposed under Global Health - EDCTP3 (work programme 2022). Further synergies and complementarities with Horizon Europe, the EU research and innovation framework programme and its partnerships (e.g. additional call for proposals under the Global Health European and Developing Countries Clinical Trials Partnership 3 –EDCTP3-Joint Undertaking) will be taken into account to maximize coherence and impact.

In order for the European Union to become a reliable partner for Africa, MAV+ must build on bilateral initiatives of EU Member States as well, and enhance the reach and coherence of the interventions by other European actors. Current EU MS support can be summarized as follows (all amounts being in euros):

- **Belgium** (Ministry of Foreign Affairs), through Enabel and in collaboration with Quamed, Sciensano, the Federal Agency for Medicines and Health Products (FAMHP) and the Institute of Tropical Medicine (ITM), is active in:
    - Senegal, 4 million project.
    - Rwanda, around 2 million contribution to project supported by the EU.
    - Supporting WHO.
- **France** (Ministry of Foreign Affairs), through AFD and Expertise France.
    - Côte d'Ivoire, 16 million.
    - Benin, Burkina Faso, Mauritania, Niger, 819,922.
    - OCEAC and UEMOA countries, 5,2 million.(including REGPharma)
    - WHO Academy, 5 million to develop training material for regulators (under discussion).
- **Germany**, through its Ministry for Economic Cooperation and Development (BMZ), Deutsche Gesellschaft für Internationale Zusammenarbei (GIZ), Physikalisch-Technische Bundesanstalt (PTB), Paul Erhlich Institute, BfArM, and Kreditanstalt für Wiederaufbau (KfW).
    - Continental actions: African Medicines Regulatory Harmonization (AMRH), RCOREs and African Medicine Agency (AMA), 10 million.
    - Quality infrastructure, up to 3 million.
    - Global health protection programme, 2,8 million.
    - SIPS, 2,8 million.
    - Ghana, 141,119 (project with EU, who contributed with 2,7 million).
    - South Africa, 33 million (13 BMZ, 20 KfW).
    - Senegal, 1 million in 2022 and 5 additional million under discussion.

More details on Team Europe activities are included in section 3.2.

Under EU and AU leadership, and in partnership with the private sector, European, African, and International financing institutions, private banks and investment funds, jointly or individually, the EU will nurture financing opportunities and vehicles to fund the establishment or expansion of infrastructures needed by regulators and in the broader biotech, pharma or healthcare technology sectors in Africa. Considering the overarching goal of strengthening health systems and pursuing universal health coverage (UHC), the EFSD+ investment windows – particularly the new Human Development Window- could incentivise and de-risk investments and promote public-private partnerships in the pharmaceutical and biotechnology sectors, and complement other actions like this one where technical assistance and exchange of know-how will predominate.

2.2 Problem Analysis

To better understand the problems and start identifying solutions, the European Commission together with France (Ministry of Foreign Affairs, Expertise France) organised in December 2021 a workshop on regulatory systems with EU Member States and key partners such as the EMA, RTD and EDCTP, World Health Organisation (WHO), World Bank, or the Bill & Melinda Gates Foundation (BMGF). Following this workshop, an analysis of the regulatory state of play has been drafted and circulated. The paper draws perspectives on collaboration between the EU and the AU and its Member States. A second workshop led by Germany (BMZ, GIZ) took place in May 2022 focusing on regulatory work in the Southern African Development Community (SADC) and involving African partners. Conclusions from both workshops confirm the importance of pursuing the objectives described in section 3 of this document. Problems could be summarized as follows:

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

The first main problem that the Action addresses is, in short, the limited access to quality-assured health products. Due to obstacles in accessing medicines and health products of good quality, affordable and in a timely fashion, the full enjoyment of the right to health remains an elusive goal for millions of people around the world. It is estimated that 2 billion people, many of whom are living in Africa, do not have access to safe and effective essential medicines and other health products.

Equitable access to health products is a global priority. The availability, accessibility, acceptability, and affordability of health products of assured quality is essential to the achievement of the Sustainable Development Goals, in particular target 3.8. Every disease management strategy requires access to health products for prevention, diagnosis, treatment, palliative care, and rehabilitation. Primary health care (PHC) services rely on access to health products, including medicines, vaccines, medical devices, diagnostics, protective equipment, and assistive devices. These products must be of assured safety, efficacy, performance, and quality, as well as being appropriate, available and affordable. The risk of poor-quality medicines remains a major threat to patients and economies.

Both the current health and economic crises have highlighted a number of critical issues that need to be addressed to strengthen the pharmaceutical environment in countries and enable a sustainable local production of pharmaceuticals, beyond COVID-19. As recognised in the World Health Assembly Resolution WHA67.20[3], regulatory system strengthening is an important building block for access to quality, safe, effective, and affordable health products.

Therefore, strengthening local manufacturing of and thereby improving access to quality vaccines, medicines and medical technologies is a priority for our African partners. It represents an opportunity not only to enhance health outcomes, but also for the EU to partner strongly with Africa and support the continent to leapfrog into sustainable innovation, and support governments and regional organisations to put in place policies and enforcement measures to organize the sector.

MAV+ and this particular action also provides an opportunity to promote gender equality and inclusion of persons with disabilities to employment. Women and persons with disabilities face particular limitations in their ability to

[3] Sixty-seventh World Health Assembly WHA67.20, 24 May 2014, Regulatory system strengthening for medical products, https://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R20-en.pdf?ua=1

access health commodities. They may have limited mobility to reach health facilities, pharmacies or vaccination sites, restricted decision-making power in their health seeking, as well as limited access to and control over resources needed for advancing their health, including information about health products safety. Also people living with disabilities and in fragile settings (like conflict areas or internally displaced) face increased difficulties in having access to safe vaccines, and medicines and other health products. 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.

b) Demographic pressure.

The African continent is today home to 1.3 billion people and accounts currently for 25% of the global disease burden. Moreover, by 2050, the population is expected to have reached at least 2 billion people. Therefore, demand of healthcare will increase in proportion.

c) Regulatory strengthening as a precondition for sustainable local manufacturing.

The COVID-19 pandemic has highlighted the vulnerabilities of existing global supply chains for all vaccines, medicines, health technologies, and products for sexual and reproductive health, and the fact that much of Africa relies on international imports. Both local manufacturing –targeted by this initiative- and the need for broadening and diversifying global value chains opens opportunities for Africa's industrial development and contributes to improve access to the essential health products.

Whilst Africa has in the order of 600 manufacturers of small molecule therapeutics, it still imports the vast majority of finished products (over 90%, and 99% of its vaccines) and is reliant on other regions for virtually all inputs (e.g., active pharmaceutical ingredients –APIs–, excipients, bottling, packaging) for local production. Increased global demand and the transport delays that were particularly debilitating for global trade during the earlier phases of the pandemic led to supply disruptions for essential medicines, compounding an already tragic situation.

Developing manufacturing capacity for medicines and other health products therefore represents an opportunity to advancing the right to health, improving resilience, and promoting inclusive development in Africa. However, improving local production and access to vaccines, medicines and health technologies in Africa is hampered by multifaceted barriers. A key challenge relates to the persistent lack of strong regulatory systems with insufficient capacity for quality assurance of health products. While national regulatory authorities are responsible for the quality, safety and efficacy of health products, the relatively weak national regulatory systems of many African countries impair efforts from applicants and national authorities to embark on local production and ensure access to essential quality, safe and efficacious medicines due to lack of skilled personnel among manufacturers and regulators and lack of knowledge of international norms and standards for health products. In addition, only countries with stable and well-functioning regulatory system (WHO maturity level 3) can meet the requirements for WHO Emergency Use Listing and Prequalification for vaccines. Furthermore, beside facilitating local production, strengthening the regulatory oversight is critical to ensuring the quality of all medical products in African countries.

These challenges at national level are aggravated by similar fragmentation and limitations at the regional level. The differences between regulatory systems in Africa causes delays for researchers and manufacturers, who must navigate multiple regulatory systems and different requirements to register the same health product in different countries.

Other challenges to local production in Africa include the need for improved approaches to post-marketing surveillance. This is highlighted by the underreporting of adverse drug reactions and adverse events following immunization and the rise in substandard and falsified products in all markets hampering efforts to ensure the quality, safety and efficacy of health products.

The entry into force of the Treaty for the Establishment of the African Medicines Agency (AMA) on 5 November 2021 marks an important milestone and highlights the urgency of making its implementation successful (more in section 2.1).

d) Regulatory strengthening as a dimension of health systems strengthening and a component of the overarching MAV+ initiative.

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

a) The **supply side (1)**

- Industrial development.
- Supply chain management and integrity (e.g. with digital tools).
- Private sector engagement.
- Quality assurance system throughout the supply process to address the constraints that negatively impact the availability, affordability and acceptability of essential medicines and vaccines and other health products, and a modern mix of quality-assured SRH-commodities.

b) The **demand side (2)**

- Market shaping, demand defragmentation and consolidation, business plans, and addressing market failures for medicines and health products.
- Health promotion and risk communication for the final users or communities.
- Building trust and confidence of local communities in locally manufactured health products.
- Trade facilitation (reduce tariff and non-tariff trade barriers for the movement of raw materials and finished products across the continent).

c) The **enabling environment and pharmaceutical / health systems**

- Regulatory strengthening. Improving regulation and governance of health products, including coherent national policies that provide the right incentives and ensuring that essential medicine lists include key commodities, including SRH commodities. (3)
- Technology transfer and intellectual property management (4).
- Access to finance, establishing financing vehicles and instruments de-risking private investments, domestic resources. (5)
- R&D, higher education and skills. Promotion of human capital development. (6)

Main stakeholders

This agenda involves numerous stakeholders at multiple levels across multiple different domains. Achieving the health objectives requires coordinated action between all partners in order to fill gaps and avoid overlaps. African actors are driving the agenda and coordinating financial and technical partners. In this sense, the European Commission has initiated dialogue and direct collaboration with the African Union Development Agency-NEPAD (AUDA-NEPAD) given their mandate and work plan to continue the harmonisation of regulations and for the establishment of the African Medicines Agency (AMA). The AMA itself will be an autonomous body and donors like the Bill and Melinda Gates Foundation are considering funding to the AMA starting 2023 or 2024.

The Commission has also started exchanges with the Partnerships for African Vaccine Manufacturing (PAVM) which includes, as part of their bold programs, a regulatory working group that is looking at support needed to NRAs and regional level to assess and approve vaccines being imported or produced locally. The regulatory bold programme is led by the head of pharmaceuticals at AUDA-NEPAD. The overall Partnerships for African Vaccine Manufacturing (PAVM) is coordinated by the Africa CDC. WHO is also offering technical assistance to make the AMA operational, and to NRAs. The World Bank has also been an important source of technical expertise, particularly in support to the RECs. CEPI, the Coalition for Epidemic Preparedness Innovations, is also entering this domain as technical partner.

The previous regional action in this domain (2021) will strengthen AUDA-NEPAD's mandate and PAVM. It will also allow the continuity of WHO's normative role, its assessment capacities and its co-leading role in the COVAX Manufacturing Task Force.

The European Medicines Agency (EMA) is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. Its mandate includes international activities and, in line with its global policy, EMA also supports access to safe, effective, and quality medicines for patients on the African continent through multiple collaborations at national, regional, and now continental levels. While the previous action (2021) empowers African and multilateral counterparts, this action (2022) aims, inter alia, at expanding the international actions of the EMA (and EU national competent authorities) and integrate the agency and its network in the ongoing discussion around the creation of AMA and regulatory strengthening in Africa, supporting African national regulatory authorities (NRAs) to achieve the minimum WHO requirements for an effective regulatory oversight of quality-assured, safe local vaccine production.

The European regulatory network (EMRN)[4] represents a unique response to the challenge of regulating human and veterinary medicines across a diverse group of countries. It includes the national competent authorities (NCAs) of the 27 EU Member States plus those of Iceland, Liechtenstein and Norway, who are responsible for medicines regulation at national level and also come together under the aegis of the Heads of Medicines Agencies (HMA) and the centralised regulator and coordinating body, the European Medicines Agency (EMA), within whose scientific committees sit representatives of those countries. The European Commission provides EU legal and supervisory authority to the Network's decisions. A model for cooperation among medicine regulators in Africa will be key to effectively supervise complex supply chains, avoid duplication of regulatory work, align regulatory approaches, and make the best use of resources.

Patients, civil society and youth organisations, products development partnerships, and health and pharmaceutical industries, welcomed the African Medicines Agency Treaty. These organisations have called all AU Heads of State to ratify the AMA treaty. The EMA and patients' organisations have been actively interacting since the creation of the Agency in 1995 providing a 'real-life' experience as well as specific knowledge and expertise to scientific discussions on medicines and on the impact of regulatory decisions. The collaboration of AMA with these groups will support transparency and improve regulatory processes.

The private sector, in its many different guises needs to be engaged to deliver the requisite progress. African pharma companies, med-tech manufacturers, private sector investors, international research & development based manufacturers, generics and med tech companies can all play a critical role and through its broad range of coordinated engagement, MAV+ will leverage the role of private sector to deliver sustainable impact.

3 DESCRIPTION OF THE ACTION

3.1 Objectives and Expected Outputs

Better regulations and better regulators are paramount to achieve development impact in the healthcare sector and particularly in the domain of access to medicines and other health products and technologies. Advancing towards regulatory harmonisation across countries, and even further, promoting new regulatory and governance paradigmes such as the use of reliance and collaborative mechanisms, results fundamental to ensure equity, quality, safety, affordability, accessibility and sustainability of pharmaceutical systems.

The **Overall Objective (Impact)** of this action is increasing **equitable access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all African**s. This objective pursues SDG 3.8 and promotes ultimately universal health coverage (UHC). Its attainment requires reinforcing African pharmaceutical systems. When the document refers to health products, it should be understood that health technologies and commodities are included.

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

1. Strengthen medicines and healthcare products regulatory systems in Africa through regulatory harmonisation, convergence and reliance mechanisms.

[4] European medicines agencies network strategy to 2025 https://www.ema.europa.eu/en/documents/report/european-union-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

This component will reinforce the role of the AMA and Africa's regulatory systems. This will be pursued in connection with SO 2 by working together with EMA and EU national regulators providing technical assistance to African counterparts (via scientific collaboration, joint inspections, trainings, etc.). Focus will be on the areas of regulatory harmonization across Africa, regulatory convergence and reliance mechanisms.

2. Enhance EU/EMA-AU/AMA cooperation, effective coordination and good governance of health products.

This component will allow the EMA and the wider EU medicines regulatory network to provide coordinated technical assistance to African counterparts at national, regional and continental level (via scientific collaboration, joint inspections, training), and notably support to AMA on the coordination of work to regulate and to monitor medicines efficiently and effectively. Section 3.5 describes the intervention logic.

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

1. Enhanced capacity of continental and national institutions in Africa to regulate medicines and other health products.
2. Regulatory harmonisation and convergence is achieved across National Regulatory Authorities (NRAs) and Regional Economic Communities (RECs) in Africa.
3. African regulatory agencies rely on each other and on European regulators.
4. Individual African NRAs progress towards their targeted individual NRA WHO maturity levels, as well as carrying out evaluations, audit, inspection and control of the quality and safety of pharmaceutical products.
5. Regulatory barriers are reduced for manufacturers in the context of product development, manufacturing, registration and vigilance. The enhancement of regulatory frameworks streamlines regulatory requirements, which will in turn facilitate submissions and thereby facilitate timely and equitable access to quality, safe and efficacious vaccines, medicines or medical devices on the continent.
6. Reduced number of counterfeit, falsified and substandard medicines and health products in Africa.
7. Increased number of professionals withwith adequate regulatory science expertise for effective medicine regulation.
8. Regulatory cooperation (via scientific collaboration, joint inspections, joint assessments, training activities) and reliance pathways is demonstrated as a viable and desirable way to improve regulatory oversight and capacity building.
9. Collaborations between regulators and industry is enhanced and supports the identification of innovative solutions for local production.

The **Outputs** to be delivered by this action contributing to the **Specific Objective (Outcome 2)** are:

1. Scientific advice by EMA is available to AMA and African regulators.
2. A robust AMA governance structure including technical committees and a more elaborated a legal framework is established.
3. Internal processes (e.g. budgetary planning) are defined, leading to an effective organisation capable of carrying out its mission and all its functions in a sustainable fashion.
3. Promoted cooperation, pooling of resources, and exchange of knowledge, ideas, and best practices between regulators at continental, regional and national levels. 4. Following the EU model, promote collaborative practices across countries, in order to benefit the entire population of Africa, and notably Sub-Saharan Africa. The existing NRA network and cooperation among medicine regulators in Africa will be reinforced. By that, actors operating in complex supply chains in Africa will be regulated efficiently and effectively, avoiding duplication of regulatory work, aligning regulatory approaches, and making the best use of resources.

All these actions complement initiatives that are being funded by the Union through national envelopes (e.g. in Rwanda and Ghana, and in the SADC region through the SIPS programme) and by EU Member States, and will

also complement activities funded by the Gates Foundation and other financial and technical partners such us the US through USAID and its contractors. More details were provided in section 2.1.

3.2 Indicative Activities

Activities related to Output 1

1.1. Accelerate the formal establishment of AMA by providing technical assistance based on WHO and EU policies, standards, procedures and guidelines for regulation and registration of key medical products (medicines, vaccines, biosimilars and other biological products, medical devices, sexual and reproductive health products, assistive technologies).
1.2. Facilitate the establishment of the AMA Secretariat.
1.3. Provide support to the AMRH/AMA technical committees upon demand from the AMRH/AMA Secretariat in close collaboration with other partners.
1.4. Continue to work at national and RECs level to strengthen and develop regulatory capacities based on AMA plans of actions for harmonisation and collaborations at the continental level.
1.5. Support the AMRH team hosted by AUDA NEPAD to continue leading the regulatory bold program under PAVM to support regulation of vaccines produced in the African continent.
1.6. Support regulatory work to be done by AMRH/AMA for specific categories of products to be regulated at continental level (e.g. development of guidelines, assessment of medicines, inspections)
1.7. Support the implementation of institutional developments plans (IDPs) of NRAs following benchmarking using the WHO GBT[5] in priority countries, in close coordination with EU Delegations, WHO and African partners. This support may include the identification of the expertise needed.
1.8. Contribute to the development of the information system of the AMA, including data sharing infrastructures based on EU experiences (e.g. EUDRA GMP database, PV database)
1.9. Support the development of regional post marketing surveillance programmes.

Activities related to Output 2

2.1. Secondment of European experts to the AMA and other African regulators, particularly in countries where MAV+ is active.
2.2. Support the development of human resource capacity for regulatory systems strengthening in Africa, including e.g. the development of a human resource and capacity development plan (gender-sensitive and inclusive of persons with disabilities).
2.3. Training and technical support is provided to enhance NRAs technical and operational capacity and progress as well as to AMRH/AMA technical committees.
2.4. EMA is duly represented and participates regularly in the AMRH Advisory Group on AMA. The active presence of EMA in this advisory group should help contribute to building the AMA regulatory framework, clarify the roles and responsibilities between AMA, RECs, and NRAs and to identify where the European expertise is most needed in line with the EU Pharmaceutical Strategy.
2.5. EMA coordinates and provides support to European regulators from EU Member States active in Africa or willing to operate in Africa (e.g. via twinning). This involves joint identification of needs.
2.6. In line with the EU regulatory system, EMA reinforces the NRA network in Africa and provides guidance for regulatory functions relevant for regional collaboration and work-sharing, and for collaboration between African regulators and the international level.
2.7. EMA shares its experience on financial sustainability and budget planning.
2.8. Support the creation of certainty for patients, healthcare professionals, industry, and governments by ensuring consistent standards and use of the best available expertise and guidance on transparency.
2.9. Share lessons learned from EU experience with African partners to reduce administrative burden and allow medicines to reach patients faster.
2.10. Accelerate the exchange of information across Africa and with Europe on important issues, such as the safety of medicines.

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

Team Europe activities should be highlighted too, building on section 2.1:

At continental level:
- The European Commission and Germany are engaging with AUDA NEPAD to support regulatory strengthening and the operationalization of the roadmap for the African Medicines Agency.
- Germany is engaging with PAVM to support its regulatory workstream (whereas EC is supporting AUDA-NEPAD).

At regional level:
- France implements the REGPHARMA project to strengthen and harmonise regulatory capacities of 14 francophone countries in Western and Central Africa at national and regional level.
- Germany is engaged in the SADC region to enhanced policy, regulatory and operational business environment on national and regional levels for the development and sustainable operation of regional value chains

At national level:
- Germany is supporting the development of the National Regulatory Authorities in Ghana and South Africa.
- The EC, France, Belgium and Germany, together with the expertise of Lithuania, Sweden, Greece and Austria, are supporting the development of the National Regulatory Authority in Rwanda
- France, Belgium and Germany are supporting the development of the National Regulatory Authority in Senegal.

The commitment of the EU's contribution to the Team Europe Initiatives foreseen under this action plan will be complemented by other contributions from Team Europe partners. It is subject to the formal confirmation of each respective partners' meaningful contribution as early as possible. In the event that the TEIs and/or these contributions do not materialise the EU action may continue outside a TEI framework.

3.3 Mainstreaming

Environmental Protection & Climate Change
N/A

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

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

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

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

Gender is an important factor influencing caregiving as well as demand, access and use of health services including immunisation services for women, adolescent girls and and children particular 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 impacts on women's and children's lives. Likewise, women are a significant majority among first line healthcare workers; their role in regulatory, safety, surveillance, clinical trials management, pharmacy, generally is growing. As such, they 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 including trainers, workers, technicians, service providers as well as managers and leaders in regulatory affairs can be supported. The action contributes to the Gender Action Plan III (GAP III, 2021-2025), more specifically area "promoting economic and social rights and empowering girls and women".

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

Human Rights

Access to quality, safe, accessible, affordable and effective health products is a human right. Human rights principles will be central in the implementation of the action. Populations in countries with lower regulatory level maturity, often excluded from access to quality health products and technologies, are also going to profit from the outcomes of this action, as one of the overarching objectives is equitable access to health products and technologies. Twining and action plans will be transparent and communication campaigns will support transparency and participation for all. Special supports from gender and human rights experts will be included during the implementation phase for analyses and studies. Particular attention will be paid to ensuring full respect for human rights and equal treatment of all.

Disability

As per OECD Disability DAC codes identified in section 1.1, this action is labelled as D1. Persons with disabilities, patients with long-term health conditions and older persons (particularly in rural areas) will benefit especially from the improved availability and quality of essential assistive technologies and quality health products in Africa. Through this Action, the European Commission and EMA and other EU regulators will work with national and international partners on regulatory frameworks and governance to contribute to and facilitate the access, availability, quality and safety of health products and essential assistive technologies necessary for empowerment of persons with disabilities in the region. The action will pay particular attention to facilitate participation of persons with disabilities in the skills building, training activities, consultations and in created employment opportunities. Accessibility to information and buildings and reasonable accommodation will be provided for participants and staff with individual needs.

Democracy

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

Conflict sensitivity, peace and resilience

The action will promote health systems resilience, pandemic preparedness and global health security. An ongoing complementary action takes into account the conflict sensitivity and reconciliation efforts in partner regions, and differences between Anglophone, Francophone and Lusophone countries. Populations in territories with unresolved and/or ongoing conflicts, asylum seekers and refugees are disproportionately affected by the current health crisis due to restrictions in movements, limited humanitarian aid and limited access to and lack of proper health 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 strengthening regulatory capacities at a national, regional and continental level is a prerequisite for allowing access to quality, safe and effective health products to population, it will attract local manufacturers as well. 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	Risk 1: - Numerous initiatives focusing on vaccine production and including the regulatory dimension leading to overlaps, duplication of efforts and inefficiencies in the support provided.	**Medium**	**Medium**	Objective 2 will enhance coordination of European regulators through EMA. Likewise, MAV+ will have a support service to ensure process are streamlined and collaboration with members of the initiative, the European Union and its Member States is efficient. There is also frequent dialogue with African and international actors.
External environment	Risk 2: - Overlapping institutional mandates (between AU and other regional organisations – RECs-, Africa CDC, AUDA-NEPAD and WHO etc.) can lead to undesired fragmentation and inefficiencies.	**Medium**	**Medium**	EU/EMA to support the roadmap of the AMRH and AMA being developed by AUDA-NEPAD and leverage the strategic dialogue to mitigate the issue of overlapping mandates. EUDs play an important role to enhance policy dialogue.
	Risk 3: Need for investment in infrastructures not covered in this action and risk aversion of private sector and financial institutions limiting investments in those infrastructures. sector.	**Medium**	**High**	Promotion of blending and guarantees to reduce financial risks on lending, and the use of technical assistance tools.
	Risk 4: Locally-produced vaccines, medicines and other health products are	**Medium**	**High**	Continue to support the WHO work to strengthen the regulatory maturity level of National Regulatory Authorities and involve all stakeholders in the

	not purchased by African governments for budget, cost, regulatory or other reasons; and continue to rely on imports.			development of innovative solutions for local production and, importantly, to incentivise a predictable demand. Involvement of global health initiatives (e.g. Global Fund, Gavi) and AVAT in MAV+ in order to gain their political and operational support.
Planning, processes and systems	Risk 5: High level of complexity given for example the array of different issues, stakeholders and partners. This could hamper strategy implementation and the realisation of impact.	**High**	**High**	The overarching strategy for the TEI will focus on the key levers that can be used to affect change, will empower African ownership and institutional development, will identify our comparative advantage, and will establish a coordination and governance initiative to monitor internal and external developments and recommend course corrections as the need arises. The specifics of follow up actions will be informed by the collective learnings of the TEI.
Planning, processes and systems	Risk 6: Low national resources (financial, infrastructure, human) made available by governments to guarantee the sustainability and viability of complex regulatory systems.	**High**	**High**	Use this action to promote reliance mechanisms to improve the efficiency of their regulatory systems. Reliance allows an authority to leverage the work performed by other authorities to decide on medical products approval within their jurisdiction. This reduces duplication of regulatory efforts, resources, and time, while maintaining national sovereignty. EUDs to advocate for countries to invest in regulatory strengthening.
People and the organization	Reduction in the current level of political interest in this agenda could hamper coordination across TEI in the longer term.	**High**	**High**	Momentum and enthusiasm amongst partners in the Team Europe Initiative will be built and harnessed through communications and awareness raising. The strategy will be developed on the basis of our full range of capabilities, whilst ensuring that different components can deliver impact in their own right.
Communication and information	Potential use of communication methods misaligned with the EC's European Commission's visual identity. Risk of low visibility inherent in acting through implementing partners.	**Medium**	**Low**	It will be mitigated by actively connecting the European Commission's EC's communications teams with the communication teams of implementing partners.

Planning, processes and systems	The high level of complexity with many stakeholders (governments/institutions, services providers, local manufacturing…) developing the sector introduce risks of corruption and/or conflict of interest	**Medium/high**	**High**	EU to support the upgrade when necessary of national pharmaceutical strategies. Continental and regional organisations and governments in Africa should be developing legal framework promoting transparency, responsible sale and rational use, and also protecting the sector against falsified medicines and vaccines with enforceable legal provisions. Legal framework has to be developed further according with experiences from AU and EU MS, WHO, UNICEF, UNFPA and in line with the UN Guiding Principles on Business and Human Rights.

Lessons Learnt:

General EC experience

The Commission has a track record of supporting pharmaceutical systems in Africa. The Commission provided EUR 25 million to finance the EU/ACP/WHO Partnership on Pharmaceutical Policies over the period 2004-2010, with a second program in the period 2011-2017 of EUR 10 million contributing to the EU/ACP/WHO Renewed Partnership to strengthen Pharmaceutical Systems in 15 Sub-Saharan countries. The evaluation report of the RP recommended to continue further developing NRAs using the Global Benchmarking Tool to assess their capacity and functionality, to advocate for adequate resources and autonomy, to pursue the harmonisation efforts through RECs and to support the establishment of AMA, to further use reliance mechanisms, to continue building capacity of staff in NRAs on various functions, to continue to promote cross border cooperation to identify and prevent the movement of substandard and falsified medical products, to support countries to expand the scope of regulated products to cover biological products, medical devices and blood products. The results of the evaluation of the latter have been taken into account to define this new action, being more targeted than previous ones. The new action being proposed now also looks at the specific value of the EU as a regional entity itself and in comparison to other donors active in this space (e.g. USAID), and intends to complement the solutions and resources offered by international/development financing institutions.

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

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. The aim is to develop robust national medicines regulatory systems and capacities for ethical reviews of clinical research and use of medicinal products and technologies in sub-Saharan Africa countries. EDCTP is one of the founder members of the African Vaccine Regulatory Forum (AVAREF) one of the technical committee under AMRH. The lessons learned from this project

based on strong collaboration between regulators and the technical committee it has supported will be helpful to support other technical committees under AMRH/AMA.

The European Medicines Agency (EMA), in cooperation with the World Health Organization (WHO), can also provide scientific opinions on high priority human medicines, including vaccines, that are intended for markets outside of the European Union. 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.

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

Existing African initiatives (PMPA, AMRH, AMA)

The African Union and its Member States have prioritised the pharmaceutical industry over the last 20 years. The Pharmaceutical Manufacturing Plan for Africa (PMPA) endorsed by the AU Heads of State and Government Summit in 2007 identified the importance of strengthening the industry and provided a basis for a raft of different initiatives that have been implemented since to address this complex agenda. The importance of regulatory strengthening and harmonisation was highlighted in the original document and is an area where the most progress has been made. The African Medicines Regulatory Harmonisation initiative (AMRH) launched in 2009 has escorted significant developments on regulatory harmonisation at the REC level and has been the precursor to the envisaged African Medicines Agency (AMA), the treaty for which has now been ratified by enough countries to be established. Further strengthening and harmonisation of regulatory systems will be essential for increasing access to affordable, effective, safe, quality essential medicines. Europe's experience in building a regional regulatory agency can be invaluable in guiding the process and building the technical capacity for its implementation. The AMRH has been implemented by the African Union Development Agency (AUDA-NEPAD) in collaboration with the national regulatory 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. In response to COVID-19 medical supply disruptions, the AMRH Steering Committee endorsed guidelines for regulatory approval, importations and procurement of COVID-19 medical devices, in-vitro diagnostics, and personal protective equipment (PPEs) for use by the AU Member States.

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

Vaccine development and manufacturing in Africa (PAVM)

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

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

EU regulatory network
Lessons learned from the cooperation and collaboration of the EU network will allow the AMA to:

- Pool resources and coordinate work to regulate medicines efficiently and effectively
- Create certainty for patients, healthcare professionals, industry, and governments by ensuring consistent standards and use of the best available expertise
- Reduce administrative burden and allowing medicines to reach patients faster
- Accelerate the exchange of information on important issues, such as the safety of medicines

3.5 The Intervention Logic

The underlying intervention logic for this action is the following:

1. Strengthen medicines and healthcare products regulatory systems in Africa through regulatory harmonization, convergence and reliance mechanisms.

This component will reinforce the role of the AMA and Africa's regulatory systems working together with EMA and EU national regulators providing technical assistance to African counterparts (via scientific collaboration, joint inspections, joint assessments, trainings, etc.), and notably the AMA. National regulatory authorities (NRAs) play a key role in promoting research and development and local pharmaceutical production whilst controlling the proliferation of falsified and substandard medicines circulating in their respective markets. While supporting national authorities is key, there is a need for regional interventions as well, particularly in light of facilitating trade of health products across countries.
Regulatory convergence represents a process whereby the regulatory requirements across countries become aligned due to the gradual adoption of internationally recognised technical guidance documents, standards and scientific principles, common or similar practices and procedures. The objectives of the AMRH/AMA include joint assessments for granting market authorisation of new or non-registered products, facilitate joint inspections of manufacturing sites, or ensure quality control in production, distribution, marketing and use. Joint work ensures quality and reduces time to perform regulatory functions. The AMRH has relied so far on donor funding from the Gates Foundation and a World Bank Trust Fund so far, meaning that support actions should also tackle the financial sustainability of the future AMA.

2. Enhance EU/EMA-AU/AMA cooperation, effective coordination and good governance of health products.

This component will allow the EMA and the wiser EU medicines regulatory network to provide technical assistance to African counterparts at national, regional and continental level (via scientific collaboration, joint inspections, joint assessments, training), and notably support to AMA on the coordination of work to regulate medicines and other health products efficiently and effectively. Due to the proliferation of donors, and potential fragmentation of actions led by different EU entities, the EMA can play a central role to ensure coherence and the best use of resources. Thanks to this intervention, EMA could proactively join and play a leading role in the AMRH Advisory Group as technical partner. EMA's technical support to AMA should be mainly focused on domains where African regulators have less expertise, such as:

- Oversight of clinical trials.
- Inspections of API manufacturers and mentoring of inspectors.
- Assessments of specific categories of products, including innovative medicines or biologicals (product assessments, inspections, and clinical trials).
- Establishment of a network of effective quality control laboratories.
- Establishment of Regional Centers of Regulatory Excellence (RCOREs) for testing vaccines to support lot release or pharmacovigilance.

The European medicines regulatory network, with the European Medicines Agency (EMA) operating at its heart, is regarded as the aspirational model for other regions of the world. No other technical partner or donor can offer this wealth of expertise. The full involvement of the EMA through this action positions the EU as a leader not only in terms of financial support to AMA and African regulators, but also technical support and scientific collaboration. This action also has a clear geopolitical implication, with EMA's good standards becoming the reference for Africa (in alignment with WHO's norms) and the EU equally benefiting from African expertise in evaluating products against endemic diseases as well. To ensure a strong EU voice in the world, it is opportune that the Commission works closely with the European Medicines Agency (EMA), the decentralised agency of the EU responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU, and the EU national competent authorities in the regulatory network.

For effective medicine regulation, medicine regulatory science expertise is essential, but additional efforts in Africa are required to strengthen national regulatory systems, to further implement regional harmonization and collaboration in regional economic communities (RECs), and to establish a continental regulatory system through the AMA. The work at national and RECs level to strengthen and develop regulatory capacities must continue together with

harmonisation and collaborations at the continental level. EMA can support national, regional and continental activities to ensure an increased efficiency of regulatory processes (e.g., reduction in time to authorise medicines and reduction in duplication of work/number of inspections by maximising reliance to focus on value-added activities), and capacity to assess complex products, as well as support on expertise gaps and support to the regional harmonization processes. In addition to supporting regulatory systems strengthening and the registration of medicines, the EU network can serve as a possible inspiration for regulators in Africa to foster collaboration between countries and regions.

3.6 Logical Framework Matrix

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

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

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

Results	**Results chain: Main expected results**	**Indicators**	**Baselines 2022**	**Targets 2027**	**Sources of data**	**Assumptions**
Impact	To increase equitable access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all in Africa, in alignment with SDG 3.8 and in the context of promoting universal health coverage (UHC).	1. UHC index 2. % of population in Africa with access to essential vaccines / medicines (disaggregated by product, country, location and gender)	To be set by the programme (MAV+) support structure once operative	10% increase (depending on product) in selected countries	1. WHO/HAI methodology to generate reliable information of the price, availability, and affordability of selected essential medicines 2.World Bank databank.	*Not applicable*
Outcome 1	1. Strengthened medicines and healthcare products regulatory systems in Africa through harmonisation, convergence and use of reliance mechanisms between regulatory authorities.	AMA starts operating as an autonomous agency, develops its organigramme and hires its own staff. 1.1.Number of personnel working for AMA (in various job categories, including managerial and administrative jobs, disaggregated by gender).	1.1. None 1.2 0 1.3 - 0 1.4 - 4	1.1. 50 persons. 1.2 - 10 1.3 - 7 1.4 - 8	1.1 AUDA-NEPAD, AU, AMRH 1.2 WHO, AUDA-NEPAD, AMA 1.3. Ditto 1.4. WHO	Financing decision is approved.

		1.2 Number and type of new regulatory guidelines developed by Technical Committes of the AMRH / AMA 1.3 Number of new guidelines approved by AMA and being implemented. 1.4 Number of African NRAs having reached maturity level 3 level based on global benchmarking by WHO.				
Outcome 2	2. Enhanced EU/EMA-AU/AMA collaboration, effective coordination and good governance of health products.	2.1. Number of EU experts mobilized to provide technical assistance to AMA and African regulators (and duration of the assignment in days/months/years) 2.2 Number of African staff trained (and skills gained).	2.1. 0 2.2. 0	2.1 10 2.2. 150	2.1 EMA 2.2. African regulators / AUDA-NEPAD	Financing decision is approved.
Output 1 related to Outcome 1	AMA starts operating. The African Medicines Agency (AMA) is established and becomes gradually operational by performing key functions according to its mandate.	Status of the African Medicines Agency (AMA): 1.1. Governance structure (organigramme) put in place. 1.2. Number of Technical committees meetings delivered. 1.3. Number of joint GMP inspections performed at RECs (regional) and AMA (continental) levels for products assigned to these levels 1.4. Number of product assessments performed at RECs and AMA levels for products assigned to these levels 1.5. Number of products registered in countries based on recommendations taken at RECs and AMA levels.	Not yet established (headquarters not selected, personnel not hired), 1.1 initial nb of TCs Not started 1.2 – 0 1.3 - 0 1.4 – 0 1.5 – 0 1.6. 18 months (dependin on product)	1.1. 50 persons. 1.2. 36 1.3. 15 1.4. 25 1.5. 25 1.6. 6 months.		

		1.6. Time reduced in medicines (or other health product) registration.				
Output 1 related to Outcome 2	2. Enhanced EU/EMA-AU/AMA collaboration, effective coordination and good governance of health products.	2.1. Number of EU experts mobilized to provide technical assistance to AMA and African regulators (and duration of the assignment in days/months/years) 2.2. Number of Technical Committees sessions supported by EU experts. 2.2 Number of African staff trained (and skills gained).				

4 IMPLEMENTATION ARRANGEMENTS

4.1 Financing Agreement

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

4.2 Indicative Implementation Period

The indicative operational implementation period of this action, during which the activities described in section 3 will be carried out and the corresponding contracts and agreements implemented, is 60 months from the date of adoption of the Financing Decision.

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

4.3 Implementation Modalities

The Commission will ensure that the EU appropriate rules and procedures for providing financing to third parties are respected, including review procedures, where appropriate, and compliance of the action with EU restrictive measures[6].

4.3.1 Direct Management (Grants)

Grants: (direct management)
(a) Purpose of the grant(s)

The grants will contribute to achieve the specific objective (SO) 1: strengthen medicines and healthcare products regulatory systems in Africa through regulatory harmonization, convergence and reliance mechanisms. The purpose will be to reinforce the role of the AMA and Africa's regulatory agencies under coordination of AMA.

(b) Type of applicants targeted

Potential grant applicants for funding would be legal entities, public bodies, international organisations, NGOs, based in Sub-Saharan Africa, and EU Member State administrations or their mandated bodies. Priority would be given to African regulators, including NRAs, RECs and the AMA.

(c) Justification of a direct grant

Where this preferred modality cannot be implemented due to circumstances outside of the Commission's control and under the responsibility of the Commission's authorising officer responsible, the grant may be awarded without a call for proposals to an African Union entity such as the African Medicines Agency (AMA) or other entity selected using the following criteria: unique role in strengthening regulations in Africa, at continental, regional or country level, and a concrete mandate as determined by applicable laws and legal texts. The treaty of the AMA explains its functions including support and coordination of National Medicines Regulatory Agencies (NMRAs).

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 there is a *de facto* monopoly in accordance with Article 195 c) of the Financial Regulation or no other entity(ies) is/are comparable in functions. However, the AMA is still in its infancy which may justify as first option a call for proposals for entities working in regulatory strengthening. A direct grant may be possible in 2023, by the time of negotiating and signing the contract.

[6] 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.

4.3.2 Indirect Management with an EU decentralised agency.

A part of this action may be implemented in indirect management through the European Medicines Agency (EMA), an EU specialized agency in medicines regulations. This implementation entails enhancing EU-AU cooperation, effective coordination and good governance of health products (SO 2). The envisaged entity has been selected based on the rationale provided in section 3.5 of this document (intervention logic).

If negotiations with the above-mentioned entity fail, that part of this action may be implemented in indirect management with an international organization (e.g. WHO). The implementation by this alternative entity would be justified because of its contribution to the access to medicines agenda and unique expertise in regulatory strengthening, and based on existing EU programmes and projects.

In case the envisaged entity (and the replacement entity mentioned above) would need to be replaced, the Commission's services may select another replacement entity using the same criteria. If the entity is replaced, the decision to replace it needs to be justified.

(d) Exception to the non-retroactivity of costs
The Commission authorises that the costs incurred may be recognised prior to the adoption of this Financing decision and as eligible as of 1 November 2022 because technical assistance activities may be initiated earlier upon request from key African counterparts.

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

If, due to reasons outside the control of the Commission, the implementation modality foreseen in section 4.3.1 (direct management through grants) is not possible, the expected financing could be implemented through indirect management with a pillar assessed entity.

If, due to reasons outside the control of the Commission, the implementation modality foreseen in section 4.3.2 (indirect management through EMA or its replacement –international organisation-) is not possible, the expected financing may be implemented through direct management through grants.

4.4. Scope of geographical eligibility for procurement and grants

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

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

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

4.5 Indicative Budget

Indicative Budget components[7]	**EU contribution (amount in EUR) for 2022**

[7] N.B: The final text on audit/verification depends on the outcome of ongoing discussions on pooling of funding in (one or a limited number of) Decision(s) and the subsequent financial management, i.e. for the conclusion of audit contracts and payments.

Implementation modalities – cf. section 4.3	
Objective 1. Strengthen medicines and healthcare products regulatory systems in Africa through regulatory harmonization, convergence and reliance mechanisms composed of	
Grants (direct management) – cf. section 4.3.1	10 000 000
Objective 2. Enhance EU leadership, effective coordination and good governance of health products composed of	
Indirect management with European Medicines Agency (EMA)	10 000 000
Evaluation – cf. section 5.7 **Audit** – cf. section 5.8	May be covered by another Decision
Totals	20 000 000

4.6 Organisational Set-up and Responsibilities

As indicated, this action contributes to the regulatory work stream under MAV+. The organizational set-up is tentative and may change over time. Particularly, frequency of meetings and participants may vary.

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

1. A High-Level Steering Committee (HLSC) to provide policy and overall strategic guidance of the programme. It reflects the high-level political dimension and the regional and continental impact of this flagship initiative, as well as the specific modalities of implementation. Thus, a Financing Agreement overarching the actions and budget committed in 2021 is currently being prepared between the EC and the AUC. The SSC will be an important vehicle for dialogue between Africa and Europe.

Meetings (1/year) will be co-chaired by the EC (INTPA Deputy Director in charge of Health) and the AUC Partnership Directorate or Department of Health. The members are representatives of AU MS and African key organisations (e.g. AUDA-NEPAD, Africa CDC, etc.) and TE (EC, EU MS and EIB).

2. At operational level, a support structure steered by the EC that includes:

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

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

The teams are already functional and meet regularly: 1/month (Flagship team), 2/months (MS Task Team), 1 every 2months (Ad-hoc project team) and 2/months (ACDC-PAVM). Even if policy steering is undertaken individually for this TEI, it is important to keep in mind the need for flexibility of the governance structure and even a potential change into a joint structure with other TEIs that would allow coordination with the other TEIs in health and/or process simplification.

b) A Technical Support Service (Secretariat) to offer the technical services needed both for supporting the MT and for the work streams coordinated implementation, monitoring and reporting. This mechanism aims at ensuring the coherent articulation of all MAV+ components and work streams in the overall TEI, and will mobilise technical and managerial expertise for capacity development and key complementary activities (e.g. knowledge management, theory of change and programme monitoring, collaboration with the private sector, etc.). Likewise, it will also underpin the PAVM and its Secretariat charged with facilitating, monitoring, tracking and reporting on implementation progress on the PAVM bold programmes. The secretariat is based on a delegated cooperation of the EC with a consortia of MS' implementing partners (agencies) and is led by a MS agency. The Secretariat could be helped by additional technical assistance and its structure is flexible, allowing new MS agencies to join in the future.

5 PERFORMANCE MEASUREMENT

5.6 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.

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

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

5.8 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 has adopted a new approach to pooling, programming and deploying strategic communication and public diplomacy resources.

Action Documents for specific sector programmes are no longer required to include a provision for communication and visibility actions promoting the programmes concerned.

However, in line with Article 46 and subject to Article 47 of the NDICI Regulation, all entities implementing EU-funded external actions shall take all reasonable measures to publicise the European Union’s support. 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.

Appendix 1 REPORTING IN OPSYS

An Intervention[8] (also generally called project/programme) is the operational entity associated to a coherent set of activities and results structured in a logical framework aiming at delivering development change or progress. Interventions are the most effective (hence optimal) entities for the operational follow-up by the Commission of its external development operations. As such, Interventions constitute the base unit for managing operational implementations, assessing performance, monitoring, evaluation, internal and external communication, reporting and aggregation.

Primary Interventions are those contracts or groups of contracts bearing reportable results and respecting the following business rule: 'a given contract can only contribute to one primary intervention and not more than one'. An individual contract that does not produce direct reportable results and cannot be logically grouped with other result reportable contracts is considered a 'support entities'. The addition of all primary interventions and support entities is equivalent to the full development portfolio of the Institution.

The present Action identifies as;

Contract level		
☒	Single Contract 1	Contribution agreement
☒	Single Contract 2	Grant

[8] Ares(2021)4450449 - For the purpose of consistency between terms in OPSYS, DG INTPA, DG NEAR and FPI have harmonised 5 key terms, including 'action' and 'Intervention' where an 'action' is the content (or part of the content) of a Commission Financing Decision and 'Intervention' is a coherent set of activities and results which constitutes an effective level for the operational follow-up by the EC of its operations on the ground. See more on the concept of intervention.