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**THIS ACTION IS FUNDED BY THE EUROPEAN UNION**

**ANNEX**

to the Commission Implementing Decision on the financing of a second special measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies and systems in Africa for 2024

**Action Document pertaining to the Second Special Measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies and systems in Africa for 2024**

**Special Measure**

This document constitutes the annual 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

<b>1. Title CRIS/OPSYS business reference Basic Act</b>	Second Special Measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies and systems in Africa for 2024  OPSYS number: ACT-62841  Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe)
<b>2. Team Europe Initiative</b>	The action will contribute to, and complement, the TEI on MAV+ (Contributing MS : BE, DE, FR, NL ; over EUR 1.3 billion in total) and the TEI on Digital Health (Contributing MS : BE, FR, DE, PT, LU, SE over EUR 130 million in total)
<b>3. Zone benefiting from the action</b>	The action shall be carried out in Africa
<b>4. Programming document</b>	N/A
<b>5. Link with relevant MIP(s) objectives / expected results</b>	This Action will complement TEI MAV+ activities funded through the regional Sub-Saharan Africa Multi-Annual Indicative Programme (RIP SSA), and will support objectives related to health in the respective benefiting African countries. It will also contribute to the Global Challenges' thematic programme objective 1: health
<b>PRIORITY AREAS AND SECTOR INFORMATION</b>	
<b>6. Priority Area(s), sectors</b>	Priority area 1 of the Sub-Saharan Africa Multi-annual Indicative Programme – Human Development, Health Sector – DAC 120; Priority area 1: People. Of the 'Global Challenges' thematic Multi-annual indicative programme 2021-2027

<b>7. Sustainable Development Goals (SDGs)</b>	Main SDG (1 only): 3 (Good health and wellbeing) Other significant SDGs (up to 9) and where appropriate, targets: SDG 1 (Poverty Reduction), SDG 5 (Gender Equality), SDG 8 (Decent Work and Economic growth), SDG 9 (Industry and innovation), SDG 10 (Reduce inequalities) and SDG 17 (Partnership)			
<b>8 a) DAC code(s)</b>	12220, Basic Health care – 15% 12250, Infectious disease control - 33% 22040 Information and communication technology (ICT) – 2% 32168, Pharmaceutical production – 50%			
<b>8 b) Main Delivery Channel</b>	Gavi - 47122 UNICEF - 41122			
<b>9. Targets</b>	<input type="checkbox"/> Migration <input type="checkbox"/> Climate <input checked="" type="checkbox"/> Social inclusion and Human Development <input checked="" type="checkbox"/> Gender <input type="checkbox"/> Biodiversity <input type="checkbox"/> Education <input type="checkbox"/> Human Rights, Democracy and Governance			
<b>10. Markers (from DAC form)</b>	<b>General policy objective @</b>	<b>Not targeted</b>	<b>Significant objective</b>	<b>Principal objective</b>
	Participation development/good governance	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
	Aid to environment @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Gender equality and women's and girl's empowerment	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Reproductive, maternal, new-born and child health	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Disaster Risk Reduction @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Inclusion of persons with Disabilities @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Nutrition @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<b>RIO Convention markers</b>	<b>Not targeted</b>	<b>Significant objective</b>	<b>Principal objective</b>
	Biological diversity @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Combat desertification @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Climate change	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	mitigation @			
	Climate change adaptation @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>11. Internal markers and Tags:</b>	<b>Policy objectives</b>	<b>Not targeted</b>	<b>Significant objective</b>	<b>Principal objective</b>
	Digitalisation @	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	digital connectivity	YES	NO	
	digital governance	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	digital entrepreneurship	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
	digital skills/literacy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	digital services	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	Connectivity @	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
digital connectivity	YES	NO		
energy	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
transport	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
health	<input checked="" type="checkbox"/>	<input type="checkbox"/>		
education and research	<input type="checkbox"/>	<input checked="" type="checkbox"/>		
Migration @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Reduction of Inequalities @	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Covid-19	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
<b>BUDGET INFORMATION</b>				
<b>12. Amounts concerned</b>	Budget line(s): 14.020120 Western Africa: EUR 93 100 000 14.020121 Central and East Africa: EUR 93 100 000 14.020122 Southern Africa: EUR 79 800 000 Total estimated cost: EUR 266 000 000 Total amount of EU budget contribution EUR 266 000 000			
<b>MANAGEMENT AND IMPLEMENTATION</b>				
<b>13. Type of financing</b>	Direct management through: - Grants - Indirect management with UNICEF			

## 1.2 Summary of the Action

In order to increase availability of, and access to, quality assured vaccines and other essential health products and technologies in Africa, this action will focus on several components along the supply chain continuum, notably the expansion of local production capacities (AVMA), health system strengthening interventions to ensure delivery and equitable access for the population at country level (Gavi 6.0), and deploying digital tools for quality assurance (UNICEF TRVST). Specifically, this action will support a set of three interventions:

### **I. Demand for vaccines produced in Africa is generated – EUR 220 million**

It is proposed to contribute to the African Vaccines Manufacturing Accelerator (AVMA), a new multi-donor pull financing mechanism which is established under Gavi. It was approved by the Gavi Board in December 2023 and launched in June 2024. The EU and Member States in a Team Europe approach announced<sup>1</sup> over EUR 750 million (USD 800 million) to the African Vaccines Manufacturing Accelerator (AVMA), including this amount of EUR 220 million, representing around 66% of AVMA's total envelop of USD 1,2 billion. AVMA aims to support the sustainable growth of Africa's manufacturing base through incentivising investments in the production of critical vaccines in Africa and to ensure demand for vaccines made in Africa. AVMA advances the demand side dimension of the MAV+ initiative and is the next step forward in achieving the African ambition of producing vaccines locally. Currently only 1% of vaccines administered to Africans are made in Africa. It is estimated that at least 4 manufacturers across various African regions will benefit from AVMA<sup>2</sup> offering sufficient support to leave a legacy of sustainable vaccine manufacturing on the continent for the long term.

### **II. Strengthened health and immunisation systems in Sub-Saharan African countries – EUR 40 million**

Gavi is a long standing EU partner which provides access to new and underused vaccines for children living in the world's poorest countries. Through this component it is proposed to contribute to Gavi's new 6.0 strategy 2026-2030 (linked to its new replenishment) with an amount of EUR 40 million earmarked for African countries. Emphasis will be given to health systems strengthening activities to ensure efficient and equitable delivery of immunisation services reaching missed communities and zero-dose children and to leave no one behind. These systems have a critical role in establishing the sustained and predictable demand for vaccines that is required for cost-effective vaccine manufacturing. In 2024, 54 countries are eligible to apply for new vaccine support from Gavi, most in Africa<sup>3</sup>.

### **III. Upscale and roll-out of digital health tools for vaccine and other essential health products counterfeit detection – EUR 6 million**

Thirdly, the action proposes the expansion of the Traceability and Verification System (TRVST), a digital traceability mechanism managed by UNICEF and inspired by the European Medicines Verification System. The EU already initiated a partnership with UNICEF under AAP 2021 in support of TRVST and the current contract is coming to an end in December of 2024. This consecutive support would allow for a roll-out of TRVST to additional African countries and to expand the system to other essential medicines and health products beyond vaccines. Linkages and synergies with MAV+, AVMA and the Africa's Centres for Disease Control and prevention (AfCDC)'s pooled procurement system and pharmaceutical initiative will be ensured. This project brings digitalization to combat the issue of falsified and substandard health products. According to United Nations Office on Drug and Crime (UNODC), trafficked medical products kill almost half a million sub-Saharan Africans every year<sup>4</sup>.

<sup>1</sup> EU contribution to AVMA: [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_24\\_3262](https://ec.europa.eu/commission/presscorner/detail/en/ip_24_3262)

<sup>2</sup> AVMA eligibility criteria: <https://www.gavi.org/programmes-impact/types-support/regional-manufacturing-strategy/avma>

<sup>3</sup> Country eligibility for Gavi support: <https://www.gavi.org/types-support/sustainability/eligibility>

<sup>4</sup> UNODC. (2023). Trafficked medical products kill almost half a million sub-Saharan Africans every year. *United Nations Office on Drugs and Crime* [Report]. Retrieved from <https://www.unodc.org>

### 1.3 Zone benefitting from the Action

The Action shall be carried out in Africa. All countries are included in the list of ODA recipients.

## 2 RATIONALE

### 2.1 Context

Africa heavily relies on supplies of essential health products from other regions. It still imports 99% of its vaccines and over 90% of its medicines. Not only it lacks producers, there is a challenge in the availability and access to health products. To give a specific example, while 56 per cent of the world has received a complete primary series of a COVID-19 vaccine, as of April 2024, only 33 per cent of the African population had been fully vaccinated. In addition, according to the World Health Organization (WHO), over 50% of people in sub-Saharan Africa lack access to essential medicines.

In light of these imbalances, in 2022 African leaders called for a New Public Health Order for Africa (NPHO) based on local ownership and leadership, equity, sustainable investment in health systems, innovation and self-reliance to position the continent to effectively address its health security challenges. Africa's New Public Health Order emphasises the importance of diversifying global value chains by increasing the share of products manufactured in Africa. The current situation with Africa importing most of its health products is not only unfair but it also presents a major challenge to global health supply chains resilience, while leaving in Africa the door open to substandard or falsified products which represent a serious public health threat.

The EU is a strong supporter of the implementation of the New Public Health Order for Africa and Health is an important area of cooperation between the African Union (AU) and the European Union (EU). Both the European Council Conclusions (EU CC) and the African New Public Health Order (NPHO) acknowledge health as a fundamental human right, emphasizing its importance for sustainable development and endorsing principles of gender equality, equity, and human rights.

In November 2022, the European Commission launched the new EU Global Health Strategy<sup>5</sup> positioning global health as an essential pillar of EU external policy and as a key component of the Global Gateway<sup>6</sup>, and established the external dimension of the European Health Union. The Guiding Principle 1 prioritises tackling the root causes of ill health, paying particular attention to the rights of women and girls, and to vulnerable populations and disadvantaged groups. It also emphasises that that Strategy is based on an approach based on human rights leaving no one behind and includes a particular focus on SRHR.

Furthermore, the EU Global Health Strategy emphasized that the EU and its Member States must play a leading role in ensuring that global health remains at the top of the international agenda, requiring effective multilateralism and inclusive multistakeholder partnerships, and serving as an essential pillar of EU external policy.

While the European Council outlines three core priorities of the EU Global Health Strategy related to healthy lives, universal health coverage and global health security, the African New Public Health Order (NPHO) focuses on five strategic pillars, which converge with EU CCs and its preceding communication through strengthened public health institutions, workforce, expanded vaccine manufacturing, increased domestic resources, and respectful partnerships. Nevertheless, both the European and the African strategies emphasize improving health and well-being, strengthening health systems, achieving universal health coverage, and preventing and combating health threats.

The 6th AU-EU Summit held in Brussels in February 2022 was instrumental in renewing and

<sup>5</sup> EU Global Health Strategy, 2022, [https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world\\_en](https://health.ec.europa.eu/publications/eu-global-health-strategy-better-health-all-changing-world_en)

<sup>6</sup> [https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway\\_en](https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway_en)

strengthening the EU-AU Partnership, as well as in defining and aligning joint priorities. EU and AU leaders agreed on a ‘Joint Vision 2030’<sup>7</sup> to support full-fledged African health sovereignty and to respond to future public health emergencies. Delivering on this strategy, the Global Gateway Africa-Europe Investment Package (GGAEIP), that aims to mobilise at least EUR 150 billion in investments, includes health as one of its five pillars.

Concrete programmes and initiatives are helping to deliver on all these health strategies. Notably in 2021 President von der Leyen backed the Team Europe initiative on Manufacturing and Access to Vaccines, Medicines and Health Technologies (MAV+) in Africa with an expected allocation of 1 billion from the EU budget. MAV+ has become a Flagship under Global Gateway. To help cover unmet needs, and also reach the target of EUR 1 billion for MAV+ from the EU budget, it was agreed within the Commission to mobilize EUR 400 million from the cushion spread over 2023 (134 million part of a special measure in 2023) and 2024 (266 million for a 2024 special measure, to which this AD refers to).

In the April 2023 letter to the European Parliament on the use of the emerging challenges and priorities cushion signed by HR/VP Borrell, Commissioner Urpilainen and Commissioner Várhelyi, it is stated the following: *‘COVID-19 has highlighted the need to ease equitable access to quality and affordable vaccines, medicines, and health technologies. We thus intend to mobilise EUR 400 million to support African partner countries, strengthening local manufacturing and their health systems, with EUR 134 million in 2023 and EUR 266 million in 2024’*<sup>8</sup>.

The previous special measure from year 2023 (on the use of 134 million from the cushion) focused on country level actions to complement ongoing efforts to facilitate production and access to vaccines in Africa through MAV+.

The focus of this second special measure also financed through the cushion will concentrate on the demand for vaccines produced in Africa (AVMA), health system strengthening interventions to ensure delivery and equitable access for the population at country level (Gavi 6.0) in African countries, and deploying digital tools for quality assurance (UNICEF TRVST).

The measure further contributes to EU Gender Action Plan III<sup>9</sup>, especially at the key thematic area Nr. 2 focuses on the promotion and protection of SRHR recognising its importance for the empowerment of women and girls in all their diversity. Women and people within marginalised groups (persons with disabilities, people from indigenous groups or ethnic minorities, etc.) face particular barriers and discrimination in accessing Sexual and Reproductive Health and Rights SRHR.

## 2.2 Problem Analysis

### Short problem analysis:

The African continent is home to 1.4 billion people representing around 18% of the world’s population and taking 25% share of the global disease burden. There is limited access to medical products and technologies needed to treat most of its population. The COVID-19 pandemic<sup>10</sup> has highlighted the vulnerabilities of existing global supply chains for vaccines, medicines and health technology products, and the fact that Africa is not part of them, which in turn hinders access to essential health products for its

<sup>7</sup> European Commission. (2022). EU-AU Partnership: Joint Vision 2030 for the Future of EU-Africa Relations. *European Union – African Union Leaders Summit*. Retrieved from <https://ec.europa.eu>

<sup>8</sup> European Commission. (2023). EU to mobilise EUR 400 million to support African health systems, strengthen local manufacturing, and ensure equitable access to vaccines and medicines. *Press Release*. Retrieved from <https://ec.europa.eu>

<sup>9</sup> European Union. (2020). EU Gender Action Plan III (2021-2025): An Ambitious Agenda for Gender Equality and Women's Empowerment in EU External Action. *European Commission*. Retrieved from <https://ec.europa.eu>

<sup>10</sup> Bell et al. (2021): “The recorded COVID-19 mortality rates were 19.2%, 11.7%, and 20.2% of the mortality rates attributable to tuberculosis, HIV/AIDS, and malaria, respectively”.



population. In addition, the scarcity of vaccine doses has led to an increased reporting of counterfeit COVID-19 vaccines posing a considerable threat to health security. The disease burden is still dominated by infectious diseases such as malaria (a main *killer* for children under 5 years old), tuberculosis and HIV/AIDs. Therefore, local manufacturing and access to quality biologicals, pharmaceuticals and medical technologies to detect and treat diseases is a priority for our African partners and represents an opportunity not only to enhance health outcomes, but also for the EU to partner strongly with Africa and allow the continent to leapfrog into sustainable innovation.

In view of these challenges the African Union (AU), G7 and G20 called for an international effort to strengthen local pharmaceutical systems and manufacturing capacity and the African Union, under the leadership of the Africa Centres for Disease Control and Prevention (CDC), launched in April 2021 the Partnerships for African Vaccine Manufacturing (PAVM) laying the foundations for the development of a biotech industry integrated into global supply chains. The AU has since put forward a vision of strengthening vaccine manufacturing in Africa so that 60% (versus current 1%) of vaccine needs can be met by Africa sources by 2040. PAVM has been renamed PHAHM, Platform for Harmonized African Health Products Manufacturing, and expanded to medicines and diagnostics.

To respond to the call from the African Union, the EU launched in May 2021 the Team Europe Initiative to support manufacturing of vaccines, medicines and health technologies in Africa (MAV+). The MAV+ policy framework revolves around three dimensions –a) supply side, b) demand side and the c) enabling environment for pharmaceutical systems– and six 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. MAV+ started in 2021 and since then the supply side and the enabling environment have received most of the attention in terms of projects.

MAV+ framework has been financed so far from several decisions resulting in continental and country level impact. At continental level, the EU is currently supporting the African Medicines Agency (AMA) and Africa Centers for Disease Control and Prevention (AfCDC), which hosts the Partnership for African Vaccine Manufacturing (PAVM), now PHAHM, AUDA-NEPAD's work on the African Medicines Regulatory Harmonization (AMRH) initiative, and WHO's mRNA technology transfer programme and its access to medicines department. This continental approach ensures that no country is left behind when it comes to promoting equitable access to health products. Country level actions are also advancing in Senegal, Ghana, Nigeria, Rwanda and South Africa. Despite the EU's substantial contribution to the local manufacturing agenda, unparalleled to other traditional donors (US, UK, etc), the AU identified an **existing funding gap** of USD 30 billion in the Framework for Action under the Partnerships for African Vaccine Manufacturing (PAVM) to reach the target for Africa to produce 60% of its own vaccine needs on the continent by 2040.

Effectively increasing availability of, and equitable access to, quality assured vaccines and other essential medicines and health products and technologies requires to act on multiple levers related to the pharmaceutical chain and health systems.

Some of the gaps identified to be addressed by this action concern generating demand for goods produced in Africa, which is what AVMA proposes. Ultimately, vaccination campaigns as developed by Gavi are also needed to reach the population. Another gap that this special measure tackles is quality assurance and combatting falsified vaccines and other health products.

### Demand

High startup costs for vaccine manufacturing and uncertain economic returns are significant barriers in setting and scaling up manufacturing facilities in Sub-Saharan Africa and challenge the commercial sustainability required for ongoing supply security.

To address these issues Gavi developed together with AU/Africa CDC the African Vaccine Manufacturing Accelerator (AVMA), which has been approved by the Gavi Board in December 2023. AVMA addresses

the critical issue of demand side barriers to manufacturing and access to health products and technologies in Africa through an Advance Market Commitment (AMC) mechanism. Advance market commitments provide assurance to subsidise yet-to-be-manufactured products in bulk if certain criteria are met.

AVMA received pledges of around US\$ 1,2 billion, which were announced at its official launch on 20 June 2024 in Paris. AVMA aims to incentivise investments in the production of critical vaccines in Africa and to provide assurance of demand for UNICEF procured vaccines. A substantial part of this funding will come from Team Europe (nearly USD 800 million, over EUR 750 million).

### Health and Immunisation Systems

Health systems, in particular in Africa, are still unprepared to cope with health emergencies while maintaining access to basic health services for their populations. More efforts are needed to enable countries to ensure the sustainable delivery of quality essential health services for the population, in particular immunization services, and to strive towards Universal Health Coverage (UHC). Gavi, the Global Vaccine Alliance, has a crucial role to play to provide support to countries in ensuring that vaccines will ultimately reach the population, particularly children. Gavi's health systems investments are targeted to improving coverage and equity of immunisation and to ensure the sustainability of immunisation programs once countries transition out of Gavi support. Without solid and resilient health and immunisation systems, the final beneficiary population will not be able to access immunisation services. Gavi's health system strengthening work focuses in particular on increasing equity of immunisation by reaching missed communities and zero-dose children with vaccines. These communities are less likely to have access to any other primary healthcare services and zero-dose children are more likely to live in households that live below the poverty line, are marginalised and are subject to multiple other deprivations. These communities are also most likely to be at the centre of disease outbreaks as they have lower levels of population immunity given inadequate access to vaccines and less capacity to detect and respond to outbreaks when they occur (given weaknesses in health systems). These systems have a critical role in establishing the sustained and predictable demand for vaccines that is required for cost-effective vaccine manufacturing. The supply chains built with Gavi support provide another critical component, also required for a healthy and diverse industry on the continent. With over 90% of vaccines used on the African continent procured via the Alliance, the Gavi 6.0 and 7.0 strategic periods that align with AVMA's lifespan, also represent complementary and necessary investments, for the objectives in 2.1 below to be realised. Indeed, up to 15% of the value of Gavi procured vaccines in Gavi 6.0, (or up to US\$900m) could be produced on the African continent under current assumptions, from a baseline of close to zero.

### Quality, effective and safe 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, particularly children and women, and particularly those from marginalised groups such as persons with disabilities, refugees, LGBTIQ persons, etc. It is estimated that 2 billion people, many of whom are living in Africa, do not have access to safe and effective essential medicines and other health products. On average, 10.5% of the medicines used in Low and Middle-Income Countries (LMICs) are sub-standard or falsified (SSF) and Africa has the highest prevalence of falsified and substandard medicines.

TRVST, a digital tool launched in 2022 by UNICEF with EU support is contributing to combatting counterfeit and falsified health products by ensuring the traceability of high-quality products making supply chains safer for all. It allows countries to verify the authenticity of health products, and to track and trace them through the supply chain on a single and common platform. The system is based on the model of the European Medicines Verification Organisation (EMVO)<sup>11</sup>. It links up a global database centralising serial numbers provided by manufacturers with country systems to verify authenticity of

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<sup>11</sup> EMVO is Belgian non-profit organisation and the European traceability system is financed by the private sector.



products along the supply chain from manufacturing to the final user. This is a low cost, high impact intervention. The system is up and running in 2 countries so far, Nigeria and Rwanda, and a third country should be connected before the end of the ongoing contract with UNICEF. Though there has been significant progress achieved in the maturation of the operational model, this needs to be further enhanced and rolled out in interested countries. As TRVST is a new system in the African Region, the alignment of stakeholders is time demanding and both a clear vision and strategy, as well as the allocation of sufficient human and financial resources will be pivotal to ensure the lasting success of the action.

With its 3 components (demand, health and immunization systems, and quality), the action will overcome bottlenecks in the effectiveness and efficiency of pharmaceutical supply chains in Africa. The action will support the supply chain continuum through expansion of production capacities, digital tools for quality assurance and targeted health system strengthening to ensure equitable access at country level.

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

The final beneficiary will be the population of African countries, in particular children requiring immunisation against infectious diseases. To achieve this, a number of stakeholders will be involved: 1) by country governments, 2) civil society organisations (including organisations working on the rights of children, women, persons with disabilities, and other vulnerabilised groups), 3) the private sector and vaccine manufacturers, etc. At regional level, AU Commission, AUDA-NEPAD, Africa CDC and African financing institutions (African Development Bank and Afreximbank), are key stakeholders together with the World Bank Group (notably IFC), Gavi, the vaccine alliance, the Global Fund to Fight AIDS, tuberculosis and malaria, WHO, UNICEF, and other multilateral and global health initiatives, foundations and programmes.

Gavi's vision is "leaving no one behind with immunisation" and aims for equitable and sustainable use of vaccines. Gavi's vaccine programmes help communities, particularly the most marginalised, build resilience and mitigate the risk of disease outbreaks. First priority are zero-dose children and missed communities (including persons with disabilities).

### 3 DESCRIPTION OF THE ACTION

#### 3.1 Objectives and Expected Outputs

Gavi is committed to increasing immunisation coverage by supporting countries to overcome gender-related barriers to accessing immunisation services and promoting equity of access for all genders, and marginalised groups to immunisation and related health services that respond to their different needs.

The **Overall Objective** of this action is to improve health of all people in Africa by increasing the availability of and equitable access to quality assured vaccines and other essential health products and technologies in Africa.

The **Specific Objectives** of this action are to:

1. Ensure demand for high-quality vaccines manufactured in Africa.
2. Increase equitable, effective and sustainable use of vaccines with particular focus on women and children and other underserved groups.
3. Ensure quality of health products in Africa.

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

- 1.1 Contributing to Outcome 1 (or Specific Objective 1): Gavi eligible vaccines are purchased

from African vaccine manufacturers.

1.2 Contributing to Outcome 1 (or Specific Objective 1): Diversified drug substance technology platforms (mRNA, viral vector, etc.) operate in Africa.

2.1 Contributing to Outcome 2 (or Specific Objective 2): Strengthened capacities of national health systems for increased equity in access to vaccine, especially among underserved population groups (including children, women, persons with disabilities, refugees etc.).

3.1 Contributing to Outcome 3 (or Specific Objective 3): The Global Trust Repository (TRVST) for vaccine and other essential medicines and health products counterfeit detection in Africa is upscaled and rolled-out.

### 3.2 Indicative Activities

Activities relating to Output 1.1:

- Provision of incentives to manufacturers for obtaining WHO prequalification (PQ) for eligible AVMA priority vaccines<sup>12</sup>. This will facilitate the local production and scale up and allow manufacturers to participate in UNICEF tenders for vaccine procurement.
- Provision of incentives to manufacturers upon delivering AVMA eligible vaccine doses<sup>13</sup>, following award through a competitively-won UNICEF tender.
- Monitor closely the eligibility criteria and disbursement triggers.

Activities relating to Output 1.2:

- Provision of incentives for the production of Gavi eligible vaccines on one of the AVMA Priority technology platforms (mRNA, viral vector). This will support the diversification and broadening of available vaccine technology platforms in Africa.

Close collaboration and complementarity will be ensured with other initiatives in support to strengthening African manufacturing of essential medicines and health products such as MAV+ to ensure the needed enabling environment and country government engagement to facilitate local production and access to local markets.

Activities relating to Output 2.1:

- Strengthening of national supply chains.
- Strengthening local capacities for community engagement and demand generation including in hard-to-reach areas and among particularly vulnerable population groups.
- Capacity building for the efficient delivery of immunisation services including leadership and management capacities.
- Strengthening national health information systems
- Strengthening of national capacities for integrated and sustainable service delivery with a particular focus on missed communities and zero-dose children including by overcoming gender and disability related barriers to immunisation.
- Support countries to prepare for transition from Gavi support by identifying and providing tailored

<sup>12</sup> Oral cholera, Malaria, Measles-rubella, Hexavalent (wP), Yellow fever, Ebola (AVMA Priority only with the following required profile: indication against at least two Ebola species and improved thermostability as from -20°C), Rotavirus (AVMA Priority only with the following required profile: single-dose blow-fill-seal presentation), Pneumococcal (AVMA Priority only with the following required profile: minimum 13-valent)

<sup>13</sup> A Gavi supported Vaccine that is WHO prequalified and Fully Manufactured within an AU member country, or, for vaccines only "Fill & Finished" in a facility within an AU member country, that facility is controlled by the holder of the WHO pre-qualification of the Qualifying Vaccine.

support to address weaknesses in critical health system functions.

- Engage with national government on health financing systems.

Support beneficiary countries to adapt their immunisation programmes to the impact of climate change and contributing to climate change mitigation<sup>14</sup> It should be noted that the Health System Strengthening strategy under Gavi 6.0 is currently under development. This action (activities under output 2) aims at contributing to the effective implementation of this strategy to be approved by the Gavi Board in 2025 and proposed activities need to be adapted accordingly.

#### Activities relating to Outputs 3.1

- Deployment of Traceability and Verification System (TRVST) in at least 9 additional African countries in close coordination with MAV+. Priority will be given to MAV+ beneficiary countries (including but not limited to: Senegal, South Africa, Ghana). UNICEF will lead the country-based negotiations between local authorities to engage in TRVST, informing INTPA HQ and EUDs.
- Capacity building measures at country level to ensure technical expertise to operate the digital tool.
- Build the necessary interface between TRVST and national logistics management information systems to ensure interoperability.
- Ensure regular technology maintenance and upgrades.
- Engage with manufacturers to join the TRVST network
- Expand the product list to be included in the platform beyond vaccines.
- Develop sustainable financing plans taking into account innovative financing models, the EMVO system, and private sector participation.
- Organise effective Steering Committee meetings with selected participants and provide documentation of agreed results, establishment of monitoring dashboards and provision of analytical reports to verify enrolment of relevant stakeholders and verification measures.

Close collaboration and complementarity will be ensured with TEI MAV+ projects such as MEDISAFE to fight falsified and substandard medicines and its successor support programme component 2, Counterfeit drugs, of the action “Countering illicit trade and Transnational Organized Crime in Africa - A targeted approach to Trafficking Corridors, Medical Products and Cybercrime (« HaltOC »)”.

The commitment of the EU’s contribution to the Team Europe Initiative to which this action refers will be complemented by other contributions from Team Europe members, It is subject to the formal confirmation of each respective member’s 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 of a TEI framework.

### 3.3 Mainstreaming

#### **Environmental Protection & Climate Change**

##### **Outcomes of the SEA screening** (relevant for budget support and strategic-level interventions)

The Strategic Environmental Assessment (SEA) screening concluded that no further action was required.

##### **Outcomes of the EIA (Environmental Impact Assessment) screening** (relevant for projects and/or specific interventions within a project)

The EIA (Environment Impact Assessment) screening classified the action as Category C (no need for further assessment).

<sup>14</sup> Within the context of the operationalisation of Gavi 6.0, Gavi is currently revising its Climate Change Approach.

**Outcome of the CRA (Climate Risk Assessment) screening** (relevant for projects and/or specific interventions within a project)

The Climate Risk Assessment (CRA) screening concluded that this action is no or low risk (no need for further assessment)

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### **Gender equality and empowerment of women and girls**

As per the OECD Gender DAC codes identified in section 1.1, this action is labelled as G1. This implies that at all stages gender-responsive human rights-based approach will guide the planning and implementation of the Action.

Gender is an important factor influencing caregiving as well as demand, access and use of health services including immunisation services for women, adolescent girls and children particularly in times of scarcity and in fragile settings, with weak health systems. Reducing scarcity and improving availability of crucial health products like the vaccines, and the availability of SRHR products, has thus a direct impact on women's and children's lives.

Therefore, gender equality and the empowerment of women and girls remain important and inherent aspects of the action, especially through its component related to primary health Care, where reproductive and sexual health care are key cornerstones. Besides, the action is committed to fostering an inclusive and representative team, ensuring that gender equality and the empowerment of women and girls are actively supported within the program's framework.

Gavi is committed to supporting countries to overcome gender-related barriers to accessing immunisation services and ensuring that all girls and boys, women and men, get equal access to appropriate immunisation and related health services that respond to their different health needs. First approved by the Gavi Board in 2008, the Gavi Gender Policy aims to increase access to immunisation through gender sensitive and where relevant gender transformative programmes in order to sustainably increase immunisation coverage. The Gender Policy was revised in 2013. Gavi has proposed the following strategic directions to pursue the goals of the revised Gender Policy: a) ensuring gender sensitive funding and programmatic approaches; b) generating, supporting, reporting, and analysing new evidence and data; c) advocating for gender equality as a means to improve immunisations coverage; and d) increasing accountability for gender-related results. Annual Reports are submitted to the Gavi Board on the progress.

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### **Human Rights**

Ensuring the highest attainable standard of health for all is a fundamental human right which requires real access to quality, safe, accessible, affordable and effective health products. Human rights principles will be central in the implementation of the action. All activities outlined in this action document will be planned and executed in alignment with the principles of a rights-based approach, good governance, human rights, and the inclusion of socially or economically disadvantaged groups.

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### **Disability**

As per OECD Disability DAC codes identified in section 1.1, this action is labelled as D1. This implies that a significant objective of Gavi's mission is to prevent disability through routine immunisation against diseases with the potential to disable such as polio. Furthermore, through its targeted investments to support delivery of immunisation services, Gavi is contributing to more integrated health systems overall, meaning countries are better equipped to provide healthcare beyond routine immunisation and understand the needs and barriers faced by children with disabilities. With immunisation comes supply chain, trained staff, data monitoring, disease surveillance, community outreach, health records, emergency coordination and social mobilisation, all of which serve as a platform for health integration with other public healthcare interventions.

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### **Reduction of inequalities**

As per the Inequality Marker, the Action is labelled as I-1. The objective of this Action is increasing equitable access to safe, effective, quality and affordable essential vaccines, medicines and health technologies for all Africans. Strengthening pharmaceutical production in African countries is a step towards making global supply chains more resilient and will be valuable in reducing cross continental and cross-country inequalities by ensuring that production also benefits non-producing African countries, with procurement for Gavi eligible countries. Furthermore, equity is a core principle of Gavi with the first priority to reach zero-dose and underimmunised children, individuals and communities.

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### **Democracy**

Although this action does not directly address democratic processes, it will play a role in enhancing good governance by bolstering national health systems and capabilities for health security. Immunised communities will be healthier and better educated, household economics will be bolstered and the next generation, both boys and girls, will grow up to become more productive members of society.

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### **Conflict sensitivity, peace and resilience**

The action will promote health systems resilience, pandemic preparedness and global health security. Populations in territories with unresolved and/or ongoing conflicts, asylum seekers and refugees are disproportionately affected by the recent health crisis due to restrictions in movements, limited humanitarian aid and limited access to and lack of proper health products. Effective, safe, and people-centred health systems are the backbone of social institutions in every country, and immunisation is often the first point of contact between these systems and the population. Through Gavi support, countries' efforts to improve equitable access to vaccines contributes to building public trust, stronger social cohesion, peaceful and inclusive societies. In addition, with a number of Gavi eligible countries facing fragility and conflict, Gavi uses a differentiated, fragility-responsive approach targeting and tailoring support to regional, national and subnational needs, including fragile, conflict and humanitarian contexts.

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### **Disaster Risk Reduction**

The impact of climate change cuts across health and well-being, livelihood, and security of people, particularly for the poorest and most vulnerable communities, such as people on the move. Immunisation is critical to building people's and systems' resilience to and reducing the risk of outbreaks due to climate-sensitive diseases, such as yellow fever, cholera and Ebola, particularly in urban, fragile and postdisaster settings. Gavi supports implementing countries to adapt their immunisation programmes to climate change and has taken steps in mitigating the carbon footprint of its programmes. For the new Gavi 6.0, the Alliance will mainstream climate change considerations into its investments and engagement across the four strategic goals.

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### **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. Immunisation protects people from

being forced into poverty due to high out-of-pocket health expenditures. Every year, healthcare costs push approximately 100 million people into poverty. Focusing on prevention rather than expensive treatment, immunisation by 2030 will help to prevent 24 million households in 41 low- and middle-income countries from slipping into poverty.

### 3.4 Risks and Lessons Learnt

<b>Category</b>	<b>Risks</b>	<b>Likelihood (High/ Medium/ Low)</b>	<b>Impact (High/ Medium/ Low)</b>	<b>Mitigating measures</b>
External environment	Numerous initiatives focusing on vaccine production leading to overlaps, duplication of efforts and inefficiencies. Projected manufacturing capacity may be higher than needs.	Medium	Medium	Close collaboration and coordination with other initiatives providing under MAV+ and others, and transparent communication around AVMA. Active INTPA participation in the Investors Forum (of core AVMA donors) and Manufacturing Forum (involving a broad cross-section of ecosystem stakeholders, including manufacturers, co-convened with Africa CDC).  Clear linkages will be established between UNICEF and MAV+.
External environment	Risk aversion of private sector and financial institutions limiting investments in health and the pharmaceutical sector.	Medium	High	Close collaboration and coordination with MAV+ projects and others, and transparent communication around AVMA. While AVMA operates as a demand side or a “pull” mechanism, MAV+ is contributing to the supply side through its industrial and access to finance pillars as “push” mechanisms.
External environment	AVMA - Inadequate enabling regulatory environment – including a well-resourced and timely WHO Pre-	Medium	High	Further advance the EU partnership with WHO and its access to medicines division, and with AUDA-NEPAD (AMRH) and EMA



	Qualification (PQ)			
.External environment	Lack of engagement/support of African states to ensure the necessary enabling environment and access to local markets	Medium	High	Close collaboration and coordination with MAV+ projects and others. Engagement with African states in the AVMA governance structures, in particular the Manufacturing Forum.
External environment	Insufficient capacity of African National Regulatory Authorities (NRAs) to ensure the Maturity Levels necessary for oversight of manufacture of Prequalified vaccine	Medium	High	Close collaboration and coordination with other initiatives to ensure that the needed regulatory environment is in place, as per above.
External environment	Gavi 6.1 - Countries may have insufficient Expanded Programme of Immunisation (EPI) team capacity and capabilities to maintain strengthen immunisation programmes and reach zero-dose communities	Medium	High	Gavi assesses capacity-building needs through a range of tools including Joint Appraisals, Programme Capacity Assessments, Effective Vaccine Management assessments, Transition Assessments and country visits. Country management capacity gaps continue to be addressed with technical assistance targeted at improving leadership, management and coordination (LMC) capacities in the EPI units; strengthening national Inter-Agency Co-ordinating Committees (ICCs) and Health Sector Coordination Committees (HSCC) by revising their mandate, membership and oversight function; and enhancing financial management.
External environment	Lack of national ownership in the implementation of immunisation	Medium	Medium	Joint donor coordination at national level and the alignment with national systems advocated by the Commission at the Board.

	programs			
External environment	TRVST.- Limited absorption capacity of new technologies and limited	High	Medium	<p>Dialogue with governments and companies to ensure the integration in national tracking systems, the expansion of the product portfolio, the interoperability and financial sustainability of the tool.</p> <p>UNICEF expanded partnership with Africa CDC includes institutional capacity support for strengthening supply chain management, incl. support for supply chain digitalization.</p>

### Lessons Learnt:

The global concentration of health products and technologies manufacturing capability and capacity in a small number of high income or high population countries (emerging economics) derived in the inequity in access to medical countermeasures during the COVID-19 response. This has led to the global call for strategic autonomy and the development of local and regional manufacturing and distribution capacities, in particular in Africa. Before the pandemic, the few available statistic showed that over 50% of people in sub-Saharan Africa lacked access to essential medicines.

The main lesson learnt from the production and value chain perspective is the need to forge multi-actor partnerships and, notably, the importance of adequately partner with governments, financing institutions , civil society organisations (including children, women and persons with disabilities rights' organisations and pooling technical expertise, which is scarce. AVMA is only one initiative in a larger ecosystem. AVMA is an important, but not sufficient condition for success, and it is dependent on partners and on broader initiatives like MAV+ that support the broader ecosystem, the supply side, and the demand side - with AVMA-).

The COVID-19 pandemic had also a disruptive effect on basic health service delivery including routine immunisation services. While health systems were able to deliver three times as many doses in Gavi-supported countries during the pandemic in order to scale-up COVID-19 vaccination, this came at the cost of routine immunisation with many countries experiencing falls in coverage and some yet to recover. This reversed years of progress in improving immunisation coverage and highlights the need to strengthen the focus on building resilient health and immunisation systems and to reaching the unreached (zero-dose children).

The development of one of the most valuable and highest-demand vaccines in history, COVID-19 vaccine, has been associated with hundreds of incidents with SF products representing risks to public health as highlighted by the COVAX Facility, the GAVI Audit and Finance Committee, and UNICEF; evidence from Interpol and the Oxford Data Observatory has corroborated this<sup>15</sup>.

The highest risk – according to UNICEF - for the distribution of counterfeit vaccines is in low- and middle-income countries national supply chains, where governance structures and traceability systems are non-existent or not fully mature, and tools and technical capacity to ensure good practices in manufacturing, quality control and monitoring of distribution chains is limited.

Digital transformation has emerged as a critical tool for health security while accelerating health system strengthening and the achievement of universal health coverage. During the COVID-19 pandemic, the

<sup>15</sup> <https://www.iddo.org/mq/research/medical-product-quality-report-covid-19-vaccines>

development and use of digital COVID certificates in support of the fight against the outbreak facilitated free movement of people and effective response to the pandemic. This illustrated the transformative impact of digital technologies on health as fundamental enabler of stronger health systems and improved health security at country, regional and global level to improve the health and well-being for all.

### 3.5 The Intervention Logic

The underlying intervention logic for this action is that the COVID-19 pandemic highlighted some major challenges in the distribution of COVID-19 vaccines leading to high inequalities in access and to unintended consequences to be urgently tackled. Currently 52% of Africans have no access to essential healthcare and essential medicines. Africa imports 99 % of its vaccine needs and less than 2% of clinical trials are conducted in the continent. This reliance on limited international manufacturing capacity led to lack of timely access to COVID-19 vaccines of African countries in the times of high global demand during the pandemic. Furthermore, the scarcity of vaccine doses led to an increased reporting of counterfeit vaccines putting at risk people's safety. At the same time countries health systems, in particular in Africa, were unprepared to cope with the emergency situation while maintaining access to basic health services for their populations.

These figures, together with the fact that infectious diseases have no borders, call for concerted action between Africa and Europe. Our health partnership is based on a shared vision towards advancing global health and improving health outcomes of our respective populations, partnering on equal footing and learning from each other, co-ownership, accountability and sustainability.

To contribute to address these problems and to complement already ongoing initiatives in the EU-AU partnership in support to diversifying the global value chain by increasing pharmaceutical production in Africa and building effective resilient health systems in the continent, the present action is composed of 3 components. Each of the 3 components will address a different bottleneck in the ecosystem of pharmaceutical supply chains in Africa as described above. The action will support the supply chain continuum through expansion of production capacities, digital tools for quality assurance and targeted health system strengthening to ensure equitable access at country level.

Component 1 will contribute to AVMA with the aim to strengthen the vaccine manufacturing capacity in Africa and respond to the challenges represented by the uneven geographic distribution of global manufacturing capacity evidenced by the COVID-19 Pandemic. The African Vaccine Manufacturing Accelerator (AVMA) is a “pull” or demand side financing mechanism to address the critical barriers to local manufacturing and access to health products and technologies by offsetting high start-up costs. AVMA is designed to de-risk the investments made by African businesses, their investors and financing partners by providing targeted financial incentives when African manufacturers vaccines receive regulatory approval from the WHO and when they win a Vaccine Alliance tender (output 1.1) and for vaccines produced using platforms that offer more resilience in a pandemic (output 1.2). As part of the MAV+ framework AVMA is ensuring the demand for vaccines being produced in Africa to facilitate needed investments in manufacturing capacity (specific objective 1). Enhancing, defragmenting and consolidating demand for products manufactured in Africa is one of the three main dimensions under the MAV+ policy framework to which this action contributes.

Component 2 will co-finance Gavi 6.0 program for 2026-2030 focusing on health systems strengthening in beneficiary countries in Sub-Saharan Africa to, in particular, strengthen the elements of their health systems which are most critical to the delivery of immunisation services and reaching zero-dose children (output 2.1). Stronger health systems will lead to more efficient and equitable health service delivery in target countries, including immunisation services. Hence the action will increase the equitable, effective, and sustainable use of vaccines (specific objective 2). This will also contribute to make African health systems more efficient and resilient and better prepared for potential future health emergencies.

Component 3 will contribute to combatting counterfeit and falsified medicines to ensure continuous availability of safe and high-quality health products for all. TRVST, a digital Global Trust repository for authenticity verification, has been launched in 2022 based on the model the European Medicines Verification Organisation (EMVO). It allows countries to verify the authenticity of health products, and to track and trace them through the supply chain on a single and common platform. It is currently implemented in 2 African countries (Rwanda and Nigeria) and the product list is limited to vaccines. Through this action, TRVST will be rolled out to additional countries in Africa and the product list broadened to include other essential medicines and health products (output 3.1). The use of the system at country combined with strengthened capacities will increase the effectiveness of detection of counterfeit and falsified health products in Africa (specific objective 3).

Consequently, the proposed action will contribute to improved access to quality health products and technologies in Africa (availability and access, quality and health systems).

### 3.6 Logical Framework Matrix

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

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

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

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

Results	Results chain (@): Main expected results (maximum 10)	Indicators (@): (at least one indicator per expected result)	Baselines (values and years)	Targets (values and years)	Sources of data	Assumptions
<b>Impact</b>	To improve health of all people in Africa by increasing the availability of and access to quality assured vaccines and other essential medicines and health products and technologies in Africa.	1 UHC service coverage index 2 DPT 3 coverage	1 68/100 in 2021 2 77% 2021	1 tbd <sup>16</sup> 2 tbd <sup>13</sup>	1 WHO 2 WHO/UNICEF Estimates of Immunisation Coverage	<i>Not applicable</i>
<b>Outcome 1</b>	To ensure demand for high-quality vaccines manufactured in Africa.	1.1 Number of vaccine doses manufactured in Africa procured with support from AVMA. 1.2 Number of African vaccine manufacturers with WHO prequalification status.	1.1 0 1.2 0	1.1 At least 130 million doses by 2030 1.2 3 by 2030	1.1 GAVI/AVMA reports 1.2 GAVI/AVMA reports/WHO	African manufacturers have access to investments

<sup>16</sup> At inception.

<b>Outcome 2</b>	To increase equitable, effective and sustainable use of vaccines in Africa with particular focus on women and children and other underserved groups.	<p>2.1 Number of children immunised disaggregated by sex and country (where possible)</p> <p>2.2 Reduction in number of Zero-dose children disaggregated by sex and country (where possible)</p>	<p>2.1 Tbd<sup>17</sup></p> <p>2.2 Tbd<sup>13</sup></p>	<p>2.1 Tbd<sup>13</sup></p> <p>2.2 Tbd<sup>13</sup></p>	<p>2.1 WHO/UNICEF Estimates of Immunisation Coverage; Country Health Information System</p> <p>2.2 WHO/UNICEF Estimates of Immunisation Coverage; Country Health Information System</p>	<p>Continued stable supply of vaccines from manufacturers</p> <p>Country applications approved by Gavi</p>
<b>Outcome 3</b>	To ensure the quality of health products.	<p>3.1 Number of countries in Africa with established detection system</p> <p>3.2. Number of counterfeit and falsified health products acted upon by detection systems supported (by type of product, by type of remedial action taken, by country)</p>	<p>3.1 2</p> <p>3.2 Tbd<sup>12</sup></p>	<p>3.1 Tbd<sup>12</sup></p> <p>3.2 Tbd<sup>12</sup></p>	3.1 UNICEF report	UNICEF expanded partnership with Africa CDC includes institutional capacity support for strengthening supply chain management, incl. support for supply chain digitalization.

<sup>17</sup> Baselines and targets will align with those included in the Measurement Framework for and Gavi 6.0 strategy being developed. These will be approved by the Gavi board in 2025.



<b>Output 1</b> <b>relating to Outcome 1</b>	1.1 GAVI eligible vaccines are purchased from African vaccine manufacturers.	1.1.1 Number of incentive milestone payments to vaccine manufacturers for obtaining WHO pre-qualification.	1.1.1 0	1.1.1 3 (2030)	1.1.1 GAVI/AVMA report	Close collaboration and coordination with MAV+ projects and others, and transparent communication around AVMA.  Incentive payments are well calibrated
		1.1.2 Number of UNICEF tenders won competitively by manufacturers supported by the AVMA	1.1.2 0	1.1.2 3 (2030)	1.1.1 GAVI/AVMA report	
<b>Output 2</b> <b>relating to Outcome 1</b>	1.2 Diversified drug substance technology platforms operate in Africa.	1.2.1 Number of drug substance platform technologies established with support of AVMA	1.2.1 0	1.2.1 2 (2030)	1.2.1 GAVI/AVMA report	Close collaboration with other initiatives on manufacturing to ensure technology transfer.
<b>Output 1</b> <b>relating to Outcome 2</b>	2.1 Strengthened capacity of national health systems for increased equity in access to vaccine, especially among particularly vulnerable population groups.	2.1.1 Vaccine stock availability at health facility level <sup>18</sup>  2.1.2 Expanded Programme on Immunization (EPI) management capacity <sup>14</sup>	2.1.1 Tbd <sup>13</sup>  2.1.2 Tbd <sup>13</sup>	2.1.1 Tbd <sup>13</sup>  2.1.2 Tbd <sup>13</sup>	2.1.1 WHO/UNICEF  2.1.2 Gavi institutional capacity assessment	Joint donor coordination at national level and the alignment with national systems and plans

<sup>18</sup> Indicators presented here are indicative. Gavi is currently developing the operationalization framework for the Health System Stengthening Strategy of 6.0, including the performance measurement framework. Work is also ongoing to define common HSS measurement within the context of the Lusaka agenda.

<b>Output 1</b>  <b>Relating to Outcome 3</b>	3.1 The Global Trust Repository (TRVST) for vaccine and other essential medicines and health products counterfeit detection in Africa is upscaled and rolled-out.	3.1.1 Number of countries in Africa connected to TRVST with support of EU.  3.1.2 Number of categories of products integrated into TRVST with support of EU.	3.1.1 2  3.1.2 1 (vaccines)	3.1.1 9  3.1.2 2 (vaccines and medicines)	3.1.1 UNICEF reports  3.1.1 UNICEF reports	Countries are interested and engaged to onboard TRSVT and countries and regional bodies are closely cooperating and coordinating and sharing their relevant data.
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## 4 IMPLEMENTATION ARRANGEMENTS

### 4.1 Financing Agreement

In order to implement this action, it is not envisaged to conclude a financing agreement with partner 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 84 months from the date of adoption by the Commission of this Financing Decision. Extensions of the implementation period may be agreed by the Commission's responsible authorising officer by amending this Financing Decision and the relevant contracts and agreements.

### 4.3 Implementation of the Budget Support Component

N/A

### 4.4 Implementation Modalities

The Commission will ensure that the EU 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<sup>19</sup>.

#### 4.4.1 Direct Management (Grants)

##### **Grants: (direct management)**

##### **Component 1 - Enhanced demand for vaccines manufactured in Africa**

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

The grant will contribute to the achievement of the specific objective 1 "Enhanced demand for vaccines manufactured in Africa" and its related expected outputs.

##### **(b) Type of applicants targeted**

Gavi, the Global Vaccine Alliance

##### **(c) Justification of a direct grant**

Under the responsibility of the Commission's authorising officer responsible, the grant may be awarded without a call for proposals to Gavi, the Global Vaccine Alliance.

Under the responsibility of the Commission's authorising officer responsible, the recourse to an award of a grant without a call for proposals for the implementation of the activities related to specific objective 1 is justified because, in accordance with article 198 (f) of Regulation (EU) 2024/2509, on account of the technical competence and administrative powers of the beneficiary.

Gavi is hosting the African Vaccine Manufacturing Accelerator and has the mandate to oversee its administration and coordination and to provide governance and treasury functions. AVMA is financing mechanism to provide a pathway to financial sustainability for eligible manufacturers by helping to offset and de-risk initial high costs of development and production of vaccines and to ensure demand through UNICEF

<sup>19</sup> [www.sanctionsmap.eu](http://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.

procurement. Gavi has also proven in the past to have the specific competency to manage similar mechanisms such as the COVAX facility.

## **Component 2 - Increased equitable and sustainable use of vaccines**

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

The grant will contribute to the achievement of the specific objective 2 “Increased equitable and sustainable use of vaccines” and its related expected outputs.

### **(b) Type of applicants targeted**

Gavi, the Global Vaccine Alliance

### **(c) Justification of a direct grant**

Under the responsibility of the Commission’s authorising officer responsible, the grant may be awarded without a call for proposals to Gavi, the Global Vaccine Alliance.

Under the responsibility of the Commission’s authorising officer responsible, the recourse to an award of a grant without a call for proposals for the implementation of the activities related to specific objective 2 is justified because, in accordance with article 198 (c) of Regulation (EU) 2024/2509, the beneficiary is in a situation of de facto monopoly.

Gavi, global Vaccine Alliance, is a global health initiative in the immunisation field, bringing together public and private sectors with the shared goal of saving lives and protecting people’s health by increasing equitable and sustainable use of vaccines and has the mandate to mobilise resources for procurement of vaccines, shaping the vaccine market, and working with countries to strengthen their immunisation systems. Gavi has a solid record of accomplishment in the immunisation field, acting at the same time as fundraiser of funding for procurement of new vaccines, shaping the vaccine market, and working with countries to strengthen their immunisation systems. Gavi spends on average US\$ 1 billion per year on delivering vaccine programmes to the 57 poorest countries.

#### 4.4.2 Direct Management (Prize(s))

N/A

#### 4.4.3 Direct Management (Procurement)

N/A

#### 4.4.4 Indirect Management with an entrusted entity

A part of this action may be implemented in indirect management with UNICEF. This implementation entails the activities contributing to the achievement of specific objective 3 “Ensured quality of health products through digital tools for detection of counterfeit and falsified health products”.

The envisaged entity has been selected based on its specific expertise and logistical capacities as well as because UNICEF has the legal mandate to manage TRVST. UNICEF is implementing the Global TRVST repository already in 2 African countries and this action is a continuation and roll out of this tool.

#### 4.4.5 Indirect Management with the Partner Country

N/A

#### 4.4.6 Contribution to <name of the relevant Regional Investment Platform>

N/A

#### 4.4.7 EFSD+ operations covered by budgetary guarantees

N/A

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

N/A

#### 4.4.9 Other actions or expenditure

N/A

### 4.5. Scope of geographical eligibility for procurement and grants

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

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

### 4.6. Indicative Budget

Indicative Budget components	EU contribution (amount in EUR)
<b>Implementation modalities</b> – cf. section 4.4	
<b>Objective/Outputs 1 “To ensure demand for high-quality vaccines manufactured in Africa”</b> composed of	220 000 000
Grants (direct management) – cf. section 4.4.1	
<b>Objective/Outputs 2 “To increase equitable, effective and sustainable use of vaccines”</b> composed of	40 000 000
Grants (direct management) – cf. section 4.4.1	
<b>Objective/Outputs 3 “To ensure the quality of health products”</b> composed of	6 000 000
Indirect management with UNICEF- cf. section 4.4.4	
<b>Grants</b> – total envelope under section 4.4.1	260 000 000
<b>Evaluation</b> – cf. section 5.2 <b>Audit</b> – cf. section 5.3	may be covered by another Decision
<b>Contingencies</b>	0
<b>Totals</b>	266 000 000

### 4.7. Organisational Set-up and Responsibilities

Gavi is governed by an international Board consisting of 28 members, including government representatives from donor and recipient countries, UNICEF, WHO, the World Bank and representatives of private sector businesses and philanthropic foundations. The European Commission is a member of a Gavi Board constituency together with Belgium, France, Germany, Ireland, and Luxemburg.

The Gavi Board is eventually responsible for giving strategic direction and policymaking to the Secretariat. The Gavi Board is advised by a number of committees set up to address specific areas of strategy development, fiduciary oversight, and audit and regularly receives financial updates with details of expenditures for Gavi programmes by year. Gavi's Secretariat is responsible for day-to-day operations, including mobilising resources from the public and private sectors, managing portfolios, providing financial, legal and administrative support, and reporting on Gavi's activities to the Gavi Board and the public.

The African Vaccine Manufacturing Accelerator (AVMA) will be integrated in existing Gavi governance processes. Two advisory forums, the Investors Forum and the African Vaccine Manufacturing Forum will be established to assist with AVMA's implementation and ensure the two-way information flow required for its smooth operation and will help align partners across the African manufacturing ecosystem and identify key bottlenecks to achieving AVMA's objectives. The decision making process will remain with the Gavi Board.

The Commission regularly engages with the decisions of Gavi through the Board and will be member of the advisory groups for AVMA and as such will be abreast of key issues in the progress of AVMA and vaccine programmes. In addition, Gavi maintains regular contact with the Commission on the progress of the action at the working level and provides formal narrative reports on the outcomes.

Gavi relies on country-based systems and works with partners with widespread field presence such as UNICEF to deliver its programmes. Driven by countries, Gavi's collaborative model has an inclusive approach which engages communities and civil society, promoting a growing ecosystem of public, private and social sector partners, bringing expertise and capacity to address countries' self-identified needs. Gavi is committed to creating a work environment that is safe and professional, where people work together in an atmosphere of mutual trust, where diversity and inclusion are valued and where everyone is treated with courtesy and respect.

As part of its prerogative of budget implementation and to safeguard the financial interests of the Union, the Commission may participate in the above governance structures set up for governing the implementation of the action and may sign or enter into joint declarations or statements, for the purpose of enhancing the visibility of the EU and its contribution to this action and ensuring effective coordination.

TRVST was developed under the Verification and Traceability Initiative (VTI), a multi-stakeholder partnership composed of UNICEF, Gavi, The Bill & Melinda Gates Foundation, the European Union, the Global Fund, USAID, the World Bank and the national regulatory authorities of Nigeria and Rwanda and governed by its steering committee. The VTI established management and coordination structures to ensure day-to-day progress in developing and deploying TRVST capability while keeping all VTI partners and key stakeholders involved in essential discussions and decisions. Governance is formed by a three-tier structure comprised of the Steering Committee, the PMU and the Task Teams. The Technical Task Teams are responsible for (i) data sharing (ii) technology management and (iii) country deployment. Currently a review of the governance structure is ongoing to ensure effective TRVST operations as we have moved into operational phase.

#### 4.8. Pre-conditions [Only for project modality]

N/A



## 5 PERFORMANCE MEASUREMENT

### 5.1 Monitoring and Reporting

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

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:

Performance and monitoring of the Action will be based on the intervention logic and the log frame matrix, including its indicators. Each implementing partner will be responsible to collect the relevant data and regularly and report on progress. Particular attention will be given to adequately assess the gender equality dimension.

For data provided by Gavi, this will align to Gavi's theory of change approach. This will provide the basis for the Gavi 6.0 measurement framework, including the indicators (incl. final mission indicators) and targets that will be brought to the Gavi Board for approval in 2025. The indicators for AVMA (output 1) already align directly to Gavi Board approved AVMA indicators.. In addition for AVMA, three triannual reviews will be conducted to enable AVMA to respond to evolving needs and circumstances. Gavi will undertake these review and course correction processes at scheduled review points in 2027, 2030, and 2033. In the context of the reviews, the Gavi Secretariat will develop course correction proposals outlining proposed strategic changes to the instrument with stakeholder engagement through a transparent and evidence-based process, with any modifications to the instrument approved by the Gavi Board.

Strategy implementation includes tracking input, process and output indicators measuring activities carried out by the Gavi Secretariat, Alliance partners and countries supporting implementation of the Gavi 6.0 strategy. Strategy performance measurement measures progress towards achievement of the strategy goals and objectives (i.e. the outputs, outcomes and impact), with shared accountability across the Alliance and reporting to the Gavi Board.

UNICEF will be responsible to regular monitor the rollout and expansion of TRVST.

### 5.2 Evaluation

Having regard to the nature of the action, a mid-term and final evaluation may be carried out for this action or its components via an implementing partner.

The mid-term evaluation will be carried out for problem solving and learning purposes, in particular with respect to the uptake and rollout of the TRVST component of the action.

The final evaluation will be carried out for accountability and learning purposes at various levels (including for policy revision), taking into account in particular sustainability aspects of the action.

Commission may, during implementation, decide to undertake an evaluation via independent consultants for

duly justified reasons either on its own decision or on the initiative of the partner, in particular to assess to what extent the action is taking into account inequality reduction as well as how it impacts the most vulnerable (bottom 40% and socio-economically disadvantaged individuals).

The evaluation reports may be shared with the partners and other key stakeholders following the best practice of evaluation dissemination<sup>20</sup>. The implementing partner and the Commission shall analyse the conclusions and recommendations of the evaluations and, where appropriate, apply the necessary adjustments.

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

### 5.3 Audit and Verifications

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

## 6 STRATEGIC COMMUNICATION AND PUBLIC DIPLOMACY

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

In line with the 2022 “[Communicating and Raising EU Visibility: Guidance for External Actions](#)”, it will remain a contractual obligation for all entities implementing EU-funded external actions to inform the relevant audiences of the Union’s support for their work by displaying the EU emblem and a short funding statement as appropriate on all communication materials related to the actions concerned. This obligation will continue to apply equally, regardless of whether the actions concerned are implemented by the Commission, partner countries, service providers, grant beneficiaries or entrusted or delegated entities such as UN agencies, international financial institutions and agencies of EU member states.

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

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<sup>20</sup> See best [practice of evaluation dissemination](#)

## 7 Appendix 1 REPORTING IN OPSYS

A Primary Intervention<sup>21</sup> (project/programme) is a coherent set of activities and results structured in a logical framework aiming at delivering development change or progress. Identifying the level of the primary intervention will allow for:

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

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

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

Primary Interventions are identified during the design of each action by the responsible service (Delegation or Headquarters operational Unit).

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

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

<b>Action level (i.e. Budget Support, blending)</b>		
<input type="checkbox"/>	Single action	Present action: all contracts in the present action
<b>Group of actions level (i.e. top-up cases, different phases of a single programme)</b>		
<input type="checkbox"/>	Group of actions	Actions reference (CRIS#/OPSYS#): N/A
<b>Contract level</b>		
<input checked="" type="checkbox"/>	Single Contract 1	Foreseen individual legal commitment for component 1.
<input checked="" type="checkbox"/>	Single Contract 2	Foreseen individual legal commitment for component 2.
<input checked="" type="checkbox"/>	Single Contract 3	Foreseen individual legal commitment for component 3.
<b>Group of contracts level (i.e. series of programme estimates, cases in which an Action includes for example four contracts and two of them, a technical assistance contract and a contribution agreement, aim at the same objectives and complement each other)</b>		
<input type="checkbox"/>	Group of contracts 1	N/A

<sup>21</sup> 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](#).