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THIS ACTION IS FUNDED BY THE EUROPEAN UNION

ANNEX

to the Commission Implementing Decision amending Commission Implementing Decision C(2021)6793 of 24.09.2021 on the financing of the Special measure in favour of contributing to the availability and equitable access to COVID-19 vaccines in low and lower-middle income countries through the COVAX Facility for 2021

Action Document for Contribution to the availability and equitable access to COVID-19 and other GAVI eligible vaccines in low and lower-middle income countries

SPECIAL MEASURE

This document constitutes the annual work programme in the sense of Article 110(2) of the Financial Regulation and action programme/measure in the sense of Articles 23 of NDICI – Global Europe Regulation.

1 SYNOPSIS

1.1 ACTION SUMMARY TABLE

1. Title/basic act/ CRIS number Basic Act	Contribution to the availability and equitable access to COVID-19 and other GAVI eligible vaccines in low and lower-middle income countries. Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI) - Global Europe. CRIS number for grant part: NDICI CHALLENGE/2021/43517
2. Team Europe Initiative	This action does not contribute to Team Europe Initiative.
3. Zone benefiting from the action/location	General beneficiaries: All low and lower-middle income countries participating in the COVAX Facility through COVAX Advance Market Commitment (AMC) financing instrument. Direct beneficiaries: The action will target 92 low and lower-middle income countries eligible for COVAX AMC support ¹

¹ Low income: Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Dem. Rep., Eritrea, Ethiopia, Gambia, The Guinea, Guinea-Bissau, Haiti, Korea, Dem. People's Rep., Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Togo, Uganda, Yemen, Rep., Lower-middle income: Angola, Algeria, Bangladesh, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Congo, Rep. Côte d'Ivoire, Djibouti, Egypt, Arab Rep., El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyz Republic Lao PDR, Lesotho, Mauritania, Micronesia, Fed. Sts., Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Príncipe, Senegal, Solomon Islands, Sri Lanka, Sudan, Timor-

4. Programming document	N/A			
5. Link with relevant MIPs objectives/expected results	N/A			
PRIORITY AREAS AND SECTOR INFORMATION				
6. Priority areas/sector(s)	Human and social development			
7. Sustainable Development Goals (SDGs)	Main SDG: <ul style="list-style-type: none"> • SDG 3: Good Health and Well-being Other significant SDGs: <ul style="list-style-type: none"> • SDG 1: No poverty • SDG 5: Achieve gender equality and empower all women and girls • SDG 10: Reduced inequalities • SDG 17: Partnerships for the Goal 			
8 a) DAC code(s)	Main DAC code: 12250 (Infectious Disease Control) – 100%			
b) Main Delivery Channel	<i>Gavi, the Vaccine Alliance – 47122</i> <i>Budgetary guarantee with EIB</i>			
9. Targets	<input type="checkbox"/> Migration <input type="checkbox"/> Climate <input checked="" type="checkbox"/> Social inclusion and Human Development <input type="checkbox"/> Gender <input type="checkbox"/> Biodiversity <input type="checkbox"/> Education ² <input type="checkbox"/> Human Rights, Democracy and Governance ³			
10. Markers (from CRIS DAC form)	General policy objective @	Not targeted	Significant objective	Principal objective
	Participation development/good governance	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input 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"/>
	Trade development	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Reproductive, maternal, new-born	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, Palestine*, Zambia, Zimbabwe. Additional IDA eligible: Dominica, Fiji, Grenada, Guyana, Kosovo*, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga, Tuvalu.

* “This designation shall not be construed as recognition of a State of Palestine and is without prejudice to the individual positions of the Member States on this issue.”

* “This designation is without prejudice to positions on status and is in line with UNSC 1244 and the ICJ Opinion on the Kosovo declaration of independence.”

² This target is specific to INTPA. If the action is marked as contributing to the Education target, please make sure the target on “Social inclusion and Human Development” is also marked.

³ Thematic target for geographic programmes (at least 15%) in delegated act.

	and child health			
	Disaster Risk Reduction @	<input type="checkbox"/>	<input checked="" 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"/>
	RIO Convention markers	Not targeted	Significant objective	Principal objective
	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 mitigation @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Climate change adaptation @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Internal markers and tags	Policy objectives	Not targeted	Significant objective	Principal objective
	Digitalisation @ Tags: digital connectivity digital governance digital entrepreneurship job creation digital skills/literacy digital services	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	Connectivity @ Tags: transport people2people energy digital connectivity	<input checked="" type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	Migration @ (methodology for tagging under development)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Reduction of Inequalities (methodology for marker and tagging under development)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Covid-19	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

BUDGET INFORMATION

12. Amounts concerned	<p>The total Union contribution is for an amount of EUR 400 000 000.</p> <p>Total EU contribution for the implementation of the grant: EUR 300 000 000 from budget line 14.02.02.40 (Global Challenges – People) in the thematic pillar.</p> <p>Total EU contribution for the EFSD+ on the Common Provisioning Fund: EUR 100 000 000 from budget line 14 020170.01 (EFSD+) from the geographic pillar.</p> <p>This action is co-financed through joint co-financing by more than 80 COVAX donors through mainly grants and guarantees.</p> <p>Total amount pledged to COVAX Facility for vaccines procurement in June 2021</p>
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	<p>is USD 9,66 billion (EUR 8,2 billion). Top 10 donor governments are:</p> <ol style="list-style-type: none"> 1. United States for an amount of USD 3,5 billion; 2. Germany for an amount of EUR 1,097 billion; 3. Japan for an amount of USD 1 billion; 4. United Kingdom for an amount of USD 733 million; 5. Italy for an amount of USD 470 million; 6. Canada for an amount of USD 384 million; 7. Sweden for an amount of USD 296 million; 8. France for an amount of USD 244 million; 9. Saudi Arabia for an amount of USD 153 million; 10. Norway for an amount of USD 141 million. <p>Top 5 Private Foundations, Corporations and are:</p> <ol style="list-style-type: none"> 1. Bill and Melinda Gates Foundation for an amount of USD 206 million; 2. Anonymous Swiss Foundation for an amount of USD 40 million 3. Mastercard for an amount of USD 32 million; 4. Reed Hastings and Patty Quillin for an amount of USD 30 million; 5. KS Relief/Gamers Without Borders for an amount of USD 26 million.
MANAGEMENT AND IMPLEMENTATION	
<p>13. Implementation modalities (type of financing and management mode)⁴</p>	<p>Direct management through:</p> <p>Grants</p> <p>EFSD+: budgetary guarantee under indirect management with EIB.</p>

1.2 SUMMARY OF THE ACTION

Despite the successful development of vaccines for COVID-19, the pandemic is still on-going and largely affects people and economies worldwide. Fragile economies of low-income countries face limited capacity to respond to the COVID-19 outbreak and handle a large number of patients. The pandemic adds significant pressure on stretched health and social service delivery systems, exacerbating vulnerabilities of the affected populations. The overall objective of this action is to mitigate the social and economic impact of COVID-19 in lower income countries by providing access to vaccines protecting from the disease. The action will support low and lower-middle income countries in their fight against the virus and address better the needs of the most vulnerable people. The objective will be achieved through supporting the availability and equitable access to COVID-19 vaccines in countries eligible to participate in the COVAX Facility through the COVAX Advance Market Commitment (AMC) financing instrument. The COVAX Facility is a pooled procurement mechanism that enters into advance purchase commitments with vaccine manufacturers to secure supply of vaccines to participating countries. The COVAX AMC is a financing mechanism intended to make COVID-19 vaccines available at low cost for 92 low- and lower-middle income countries.

⁴ Art. 27 NDICI

With the World Health Organization (WHO) having declared the end of COVID-19 as a public health emergency of international concern (May 2023), the COVAX Facility is being transformed into a COVID-19 programme, aiming at integrating COVID-19 vaccines in routine immunisation programs and the actions undertaken to mitigate the impact of the pandemic are being turned into sustainable long term investments.

The COVID-19 pandemic has brought to the fore the challenges represented by the uneven geographic distribution of global manufacturing capacity. Africa currently imports 99 % of its vaccine needs and relies on limited international manufacturing capacity, which is constrained in times of high global demand. Following access, equity and supply security issues, the African Union (AU), G7 and G20 called for an international effort to improve access to medical countermeasures to better prepare for future health emergencies. The EU has launched the Team Europe Initiative to support manufacturing of vaccines, medicines and health technologies in Africa (MAV+).

In addition, the COVID-19 pandemic severely affected access to basic health services, including immunisation services hampering progress in immunisation routine coverage and resulting in an increase in zero-dose children.

These factors have led to support the strengthening of African vaccine manufacturing while continuing to provide the needed COVID-19 vaccines and strengthen routine immunisation.

2. RATIONALE

2.1 CONTEXT

Despite the successful development of vaccines, the end of the pandemic is not yet in sight. The roll-out of vaccinations has begun in many parts of the world, yet distribution and access vary greatly. This puts everyone at risk, as it allows for the virus to mutate and generate new variants. Moreover, the uneven access will likely lead to differences in the ability of countries to recover from this crisis and increase inequalities. Immunisation is one of the most effective public health interventions – both in terms of lives saved and in terms of economic benefits. Immunisation currently prevents 2-3 million deaths every year from diseases like diphtheria, tetanus, pertussis, influenza and measles. There are now vaccines to prevent more than 20 life-threatening diseases, including COVID-19.

Only a year after COVID-19 the new coronavirus emerged, the first vaccines to protect against it are in use. The accelerated development of multiple vaccines is unprecedented, as in normal circumstances the process takes eight to fifteen years. Currently about a dozen of vaccines have been approved for general or emergency use in countries around the globe, while hundreds of other candidates are still undergoing development and clinical testing process, requiring further investments.

Following a call by the G20 under the Saudi Presidency, at an event in April 2020 co-hosted by the President of the European Commission, the Director General of the World Health Organization, and the Bill and Melinda Gates Foundation, and several EU Member States, the Access to COVID-19 Tools (ACT) Accelerator was launched. Different organisations have joined forces to end the pandemic by supporting the development and equitable distribution of the tests, treatments and vaccines the world needs to reduce mortality and severe disease, restoring full societal and economic activity globally in the short term, and facilitating high-level control of COVID-19 disease in the medium term. Since then, the Commission has decidedly supported the ACT-Accelerator, notably through the Coronavirus Global Response Pledging Conference, which successfully forged an

unprecedented political collaboration amongst more than 50 governments, non-profits and private donors from all continents. The goal of this event was to ensure the universal and equitable access to prevention, diagnostic and treatment against COVID-19, and to strengthen health systems. The total amount announced on 4 May 2020 was EUR 7.4 billion (USD 8 billion), matching the initial estimations by the Global Preparedness Monitoring Board experts on resources needed immediately for the development, manufacture, and deployment of new COVID-19 technologies. After the event, a pledging marathon started and resources mobilised surpassed EUR 9.8 billion in the following weeks. The visibility of the event persuaded over 20 countries and organisations to provide new or increased contributions in the following days. In addition, the ‘Global Goal: Unite for our Future’ pledging summit organised by the Commission and Global Citizen on 27 June 2020 mobilised an additional EUR 6.15 billion to ensure equitable access to COVID-19 vaccines, tests and treatments, support health systems and enhance global health security. Therefore, almost EUR 16 billion have been mobilised in the form of grants, loans and guarantees.

Co-led by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI), and the World Health Organization (WHO), COVAX is one of the pillars of the Access to COVID-19 Tools Accelerator, a ground-breaking framework for collaboration that brings together governments, health organisations, scientists, businesses, civil society, and philanthropists to speed up efforts to end the pandemic by supporting the development and equitable distribution of the vaccines, diagnostics and treatments the world needs. While Gavi is the legal entity administering the COVAX Facility, the three leading organisations work together to fund development and manufacturing activities, to finance the procurement and to deploy COVID-19 vaccines in a fair and equitable manner. The initial goal was to secure and deliver 2 billion vaccine doses by the end of 2021, including 1.3 billion vaccine doses for 92 low and middle-income countries. The latter goal was recently raised to 1.8 billion doses, allowing vaccinated population coverage to increase from 20% to 30%. To achieve this, COVAX needs to raise at least USD 8.2 billion for low and lower-middle income countries.

On 31 August 2020, the Commission made a political announcement to support the COVAX facility by channelling EUR 400 million from the European Fund for Sustainable Development (EFSD) guarantees, which were made available to Gavi through the European Investment Bank (EIB). The EFSD contribution was then complemented by a EUR 100 million grant financed from the 11th European Development Fund (EDF) general reserve⁵.

At the G7 virtual leaders’ meeting of 19 February 2021, President Ursula von der Leyen announced an additional EUR 500 million for the COVAX Facility, doubling the EU contribution up to EUR 1 billion, with new EUR 300 million in grant and EUR 200 million in EFSD+ guarantees to EIB loan.

To date, there are 191 countries participating in the COVAX Facility. The funding for vaccines for 99 upper middle- and high-income countries is pooled from their domestic health funds, as they participate in the COVAX Facility as self-financing participants (SFP). The second pillar of the Facility is COVAX Advance market commitment (AMC) financing mechanism, which aims to support the procurement and delivery of vaccines for 92 low and lower-middle income countries, as well as other International Development Association (IDA) eligible economies, ensuring that they have access to COVID-19 vaccines at the same time as wealthier economies. The group of 92 AMC countries are composed of those with a gross national income (GNI) below USD 4000. AMC countries will need to co-finance a COVID-19 vaccine in the medium to long term as it is with all routine vaccine programmes supported by Gavi. Launched in June 2020, the Gavi COVAX AMC is

⁵ Decision EDF 2020/042-956

already delivering on the ground to benefit 92 lower income economies. The first doses arrived on 20 January 2021 in Asia and 24 February in Africa – less than three months after the first higher income countries started their own immunisation programmes. COVAX Facility has assembled a broad portfolio of vaccine candidates and vaccines, based upon diverse technologies and geographies and has already secured 2,1 billion doses from legally binding agreements and deals under negotiation.

Without a successful COVAX Facility, there would be a real risk that lower income countries would be left behind, unable to negotiate fair prices and allocation conditions on their own. Consequently, the vast majority of people in the world would go unprotected. This would allow the virus and the pandemic to continue unabated and disrupt the global economy.

In May 2023, the World Health Organization (WHO) declared the end of COVID-19 as a public health emergency of international concern. Within this new context, COVAX processes have been transitioned into GAVI business aiming at integrating COVID-19 vaccination in routine immunisation programs.

Given remaining resources, donors have the possibility to widen the scope of their funding to respond to the experienced bottlenecks in pandemic prevention, preparedness and response while at the same time continue to ensure the provision of needed COVID-19 vaccines to GAVI eligible countries as well as support routine immunisation and address the pressing challenge of zero-dose children.

2.2 PROBLEM ANALYSIS

Priority area and sectors

The primary objective of the action is to address the immediate public health needs of the low income countries in fighting against the COVID-19 outbreak via the provision of equitable access to vaccines, to respond to the experienced bottlenecks in pandemic prevention, preparedness and response and to further support the building of resilient immunisation systems in GAVI eligible countries. Developing and having access to a vaccine against COVID-19 is a pressing challenge for ending the pandemic worldwide. Preventing the spread of this infection through the vaccination is the most cost-effective public health intervention to control the pandemic.

Despite of the tremendous global effort to ensure equitable access to C-19 vaccines, Africa has been unable to achieve significant COVID-19 vaccination coverage⁶, to a great extent due to the continent's dependency on limited international manufacturing capacity which is constrained in times of high global demand. Following these access, equity and supply security issues experienced during COVID-19, the African Union (AU), G7 and G20 called for an international effort to improve access to medical countermeasures to better prepare for future health emergencies. This has led to support for the strengthening of African vaccine manufacturing.

In general, all countries participating in the COVAX Facility will ultimately benefit from this joint mechanism. More precisely, this particular action will target as direct beneficiaries the 92 COVAX eligible economies, which are also eligible under the NDICI Regulation.

⁶ As of April 2024, 40% of the population received at least one dose and 33% completed the complete primary series against a 70% coverage target (WHO Africa COVID-19 Vaccination Dashboard <https://app.powerbi.com/view?r=eyJrIjoiYWJiNDNiZDItYmViZS00NWQ2LTgwNDQtY2JmNTM5NTNINDM0IiwidCI6ImY2MTBjMGI3LWJkMjQtNGIzOS04MTBiLTNkYzI4MGFmYjU5MCIsmiOjh9>).

Short problem analysis

The EU Strategy for COVID-19 vaccines announced in June 2020 stressed that a global recovery will only be possible through universal, equitable and affordable access to effective and safe COVID-19 vaccines. In line with this principle, the EU leads the international response to COVID-19 through multilateral initiatives to develop and distribute vaccines globally and is supporting the COVAX Facility, the global initiative to ensure rapid and equitable access to COVID-19 vaccines for all countries. The EU, its Member States and European financial institutions are among the largest contributors to COVAX with more than EUR 3.2 billion committed to help procuring vaccines for 92 low and middle-income countries by the end 2021. The action is in line with the partner countries' policies and strategies directed at tackling the COVID-19 crisis, mitigating the long-term socio-economic impact and reducing pressure on health care systems.

In addition, on 19 January 2021, the Commission adopted a Communication "A united front to beat COVID-19"⁷. It proposed to set up an EU vaccine sharing mechanism to help share part of doses already secured by the EU for own needs. It would primarily benefit health workers and priority groups with humanitarian needs. The Team Europe approach aims at donating at least 100 million doses of vaccines to low and middle-income countries until the end of the year 2021, in particular through COVAX.

A fair allocation mechanism for COVID-19 vaccines through the COVAX Facility will identify the priority target groups. Target populations will be grouped into tiers that would have progressive access to the vaccine. WHO advises that once vaccines are proven to be safe and effective, and authorised for use, all countries receive doses in proportion to their population size, albeit initially in reduced quantities. This will enable every country to start by immunizing the highest priority populations. Vaccines would continue to be deployed in a second phase. In summary, fair allocation of vaccines will occur in the following way:

1. An initial proportional allocation of doses to countries until all countries reach enough quantities to cover 20% of their population. Tier 1 (or the priority group) could potentially include frontline workers in health and social care settings, people over the age of 65 years, and people under the age of 65 years who have underlying conditions that put them at a higher risk of death.
2. A follow-up phase to expand coverage to other populations. If severe supply constraints persist, a weighted allocation approach would be adopted, taking account of a country's COVID-19 threat and vulnerability.

The COVID-19 pandemic has highlighted the vulnerabilities of existing global supply chains for vaccines, medicines and health technology products, which in turn hinders access to essential health products for its population. Africa currently imports 99% of their vaccines and more than 90% of all their medicines and health technologies. Therefore, local manufacturing and access to quality biologicals, pharmaceuticals and medical technologies is a priority for our African partners, and represents an opportunity to enhance health outcomes.

⁷https://neighbourhood-enlargement.ec.europa.eu/news/commission-sets-out-key-actions-united-front-beat-covid-19-2021-01-19_en

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 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.

To respond to the call from the African Union, the EU has launched the Team Europe Initiative to support manufacturing of vaccines, medicines and health technologies in Africa (MAV+).

To contribute 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 as one of the proposed initiatives to reallocate COVAX remaining funds. 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). AVMA aims to make up to US\$ 1 billion available to manufacturers over 10 years helping offset high start-up costs and provide assurance of demand for UNICEF procured vaccines. A substantial part of this funding would come from Team Europe Initiative.

Both the MAV+ European initiative and the Partnership for African Vaccine manufacturing (PAVM; now PHAHM) coordinated by the AfCDC, launched in 2021, identified demand consolidation and market shaping as critical areas for intervention. Therefore, AVMA advances the creation of a market for African products and is one of the projects that MAV+ and European donors support. MAV+ covers many other complementary areas to make local production sustainable. MAV+ offers a 360-degree approach along a) the supply side, b) the demand side, and c) the enabling environment; 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 and 6) R&D, higher education and skills.

Main stakeholders

The populations of the eligible to COVAX AMC support low income countries will be the main beneficiaries of the action. As rights-holders, they are approached as active stakeholders whose participation is supported by dedicated activities. This is particularly true in the case of COVID-19 where people participation is a critical success factor of containment measures.

Among them, the action will primarily address vulnerable populations (including elderly women and men, people with disabilities, people residing in conflict-affected regions, women and men belonging to minorities, and others). This is because their degree of exposure to the virus and risk profile (morbidity and mortality) are higher than for other groups.

Healthcare professionals and workers are at the forefront of the fight against COVID-19 in all countries. According to the “fair allocation mechanism” proposed by the WHO, they will be the first to receive preventive vaccination.

National authorities, in particular ministries of health, ministries of labour and social security, ministries of emergency situations and public institutions supporting gender equality will benefit from the action. Ministries of finance will be involved by deciding on the possibility to participate

with own co-funding in the acquisition of vaccines. The role of the COVAX Facility as the provider of COVID-19 vaccines will be also important in advising and supporting the authorities on the further deployment of vaccines within their countries.

The AU and Africa CDC and national regulatory agencies are key stakeholders in the efforts to strengthen local manufacturing and the pharmaceutical manufacturing sector will play a key role in setting and scaling up manufacturing capacity in Africa.

WHO is key enabler through its pre-qualification process for pharmaceutical products.

A well-coordinated effort with aid organisations (UN Agencies, Red Cross and Red Crescent, INGO) will be crucial for efficient delivery and other initiatives (MAV+) in support to strengthening local manufacturing capacity.

3. DESCRIPTION OF THE ACTION

3.1 OBJECTIVES AND EXPECTED OUTPUTS

The Overall Objective (Impact) of this action is to mitigate the social and economic impact of the COVID-19 pandemic in low and lower-middle income countries and to reduce morbidity and mortality of vaccine preventable diseases. The action will implement EU's solidarity support by contributing to the equitable access to vaccines and help prevent the transmission of COVID-19 and other vaccine preventable diseases around the world.

The Specific Objectives of this action are:

1. To purchase COVID-19 vaccines through the EU-funded intervention for COVAX AMC eligible countries, especially to priority groups identified (e.g. healthcare workers, elderly, vulnerable and high-risk people).
2. Strengthened vaccine manufacturing capacity in Africa.
3. Improved immunisation coverage of GAVI eligible vaccines.

The Outputs to be delivered by this action contributing to the corresponding Specific Objective are:
Output 1.1 contributing to Specific Objective 1: COVID-19 vaccines are procured for COVAX AMC countries.

Output 2.1 contributing to Specific Objective 2: GAVI eligible vaccines purchased from African vaccine manufacturers.

Output 2.1 contributing to Specific Objective 2: Drug substance platform technologies established on the African continent.

Output 3.1 Contributing to Specific Objective 3: Children vaccinated with Gavi-supported vaccines.

3.2 INDICATIVE ACTIVITIES

Activities related to Output 1.1:

- Upfront investment in manufacturing capacities, so vaccines can be produced at scale as soon as they are proven successful, safe and efficacious.
- Sharing the risks associated with vaccine development.
- Pooling procurement and purchasing power to achieve sufficient volumes at acceptable prices.

- Advance purchase agreements to reserve doses of vaccines for eligible economies.

Activities related to Output 2.1:

- Support substantial and sustainable vaccine production capacity in Africa.
- Support WHO prequalification for vaccines produced by African manufacturers for priority vaccines⁸.
- support diversification and broadening of vaccine portfolio from African manufacturers.
- support the diversification and broadening of available vaccine platform technologies in Africa (mRNA, viral vector, protein sub-unit etc.).

Activities related to Output 3.1:

- Support countries' vaccination strategies in line with their needs
- Procurement and shipment of vaccines to beneficiary countries
- Delivery for in-country distribution and administration of vaccines
- Support countries to introduce and scale up coverage of vaccines for prevention of endemic and epidemic diseases.

3.3 MAINSTREAMING

Environmental Protection & Climate Change

N/A

Gender equality and empowerment of women and girls

Gender is an important factor influencing demand, access and use of health services including immunisation services in COVAX-eligible countries. Likewise, women are a significant majority among first line healthcare workers that are involved in the fight against COVID-19 pandemic. As such, they will be the first to profit from the vaccination once available, which will both protect them personally from getting sick and allow continuing their duties to care about other patients. Outreach and social mobilisation of both women and men could lead to higher rates of immunisation. Cultural barriers may prevent female caregivers from seeking immunisation services from male health workers. In these settings, initiatives to increase the number of female service providers can help improve access to immunisation.

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.

⁸ All GAVI-supported vaccines are included in scope, with the following ones (with specific relevance to pandemic preparedness) receiving additional incentives: Oral Cholera, Malaria, Measles-Rubella, Hexavalent, Yellow Fever; Rotavirus; Pneumococcal

Human Rights

Human Rights principles will be central in the implementation of the action. Vulnerable and fragile groups are also going to profit directly from the outcomes of this action, as provided for in the WHO fair distribution list for getting COVID-19 vaccines. A particular attention will be paid to ensuring full respect for human rights and equal treatment of all. Persons with disabilities and pre-existing conditions (particularly girls, women and elderly) may be at greater risk due to inaccessible information about COVID-19 and other vaccination and may experience barriers to accessing health services.

Disability

As per OECD Disability DAC codes identified in section 1.1, this action as D0.

Democracy

The pandemic has challenged not only health and economic systems, but also adversely impacted already fragile conditions for democracy. Due to the emergency measures, the pandemic also took a heavy toll on electoral processes and freedom of assembly. The COVID-19 crisis opened the door to new risks of increased inequality and disinformation that undermines credibility of the EU and state authorities. This action will complement the EU's efforts to strengthen democratic and civic resilience in the low and lower-middle income countries through supporting equitable access to vaccination, allowing a gradual return to normalcy for people.

Conflict sensitivity, peace and resilience

The action takes into account the conflict sensitivity and reconciliation efforts in partner regions. Populations in territories with unresolved and/or ongoing conflicts, asylum seekers and refugees are disproportionately affected due to restrictions in movements, limited humanitarian aid and limited access to and lack of proper health care services. Secured by COVAX AMC donor funding, the COVAX Facility foresees the distribution of at least 100 million doses through its Humanitarian Buffer to those regions and territories most in need. In addition, GAVI is revising its approach to fragility in its core vaccination program as to ensure to reach the most vulnerable and most in need including zero dose children.

Disaster Risk Reduction

COVID-19 pandemic has created a big damage to societies and economies globally. Preventing the spread of this infections and development of new pathogen variants is a prerequisite for returning to normality. Vaccination is the only proven and efficacious prevention method, which required great quantities of vaccines equally distributed in the world. This measure will contribute to this global goal directly. Immunisation is also 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 post disaster settings.

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 LESSON LEARNT

Experience from past outbreaks of diseases, ongoing challenges and reports on the health system capacity of lower income countries demonstrated that the health system capacity of these countries to deal with health emergencies faces persisting challenges.

Gavi is a global initiative with a solid record of accomplishment in the immunisation space. Since Gavi was established in 2000, its mission to save lives, reduce poverty and protect the world against the threat of epidemics has helped vaccinate more than 822 million children in 73 countries through the end of 2019, preventing more than 14 million future deaths.

The EU is working with Gavi since its creation and supported its other activities with more than EUR 200 million until now and with the first EUR 500 million package of 100 million grants and EUR 400 million of EU Guaranteed EIB loans to COVAX.

For the latter, the Commission, Gavi and EIB successfully put together a complex financial package for COVAX Facility to bridge-finance the manufacturing of vaccines while donor pledges are being turned into actual payments. The 100% EU risk cover has allowed the EIB to finance these loans to Gavi and they have already disbursed the EUR 400 million for COVAX. Gavi has expressed great satisfaction with the efficient deployment of this bridge loan.

For the new period of 2021-2025, the Commission has pledged to support Gavi with EUR 300 million.

The Multilateral Organisation Performance Assessment Network (MOPAN) carried out an institutional assessment of Gavi, the Vaccine Alliance, covering the period from 2014 to mid-2016. The assessment considered organisational systems, practices and behaviours, as well as the results that Gavi achieves. The overall conclusion of the 2016 MOPAN assessment is that Gavi meets the requirements of an effective multilateral organisation and is fit for purpose. Areas, where performance could be strengthened and improved, include clarification of Gavi's role and function at the country level and a clearer results framework for health system strengthening interventions.

However, global initiatives cannot operate in a vacuum. They depend on strong national health systems and efficient delivery mechanisms to sustain the gains achieved. Effective health systems improve compliance of medical treatments and prevent resistance, provide adequate surveillance and response systems. Only when we are successful in helping to establish effective health systems, can the impact of important vertical initiatives like Gavi be optimal. The Commission therefore works with its EU Delegations managing bilateral health programmes and with EU Member States to help coordinate the various health programmes to achieve maximum impact.

In the race to ensure proper and equitable worldwide coverage through vaccination, Gavi will serve as an administrative unit and financial guarantee for COVAX Facility. The governance structure already put in place will ensure that it operates in a transparent and effective manner with minimal risks.

The emergence of COVID-19 pandemic has imposed unprecedented challenges at global and continental levels on public health and the economy, and also on society as a whole. It has significantly disrupted the production and supply of much needed medicines, vaccines and other health products including those required to effectively respond to the pandemic itself. The COVID-19 situation highlights a need for regulatory agility in order to respond to the pandemic and to enable priority essential medical products of assured quality, safety, and efficacy to be rapidly developed, manufactured, assessed, and supplied.

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.

The COVID-19 pandemic had also a disruptive effect on basic health service delivery including routine immunisation services. This highlights the need to strengthen the focus on building resilient health and immunisation systems and to reaching the unreached (zero-dose children).

Category	Risks	Likelihood (H/M/L)	Impact (H/M/L)	Mitigating measures
External environment	Actual price of authorised vaccines is much higher than anticipated	M	M	Additional co-funding from other partners and sources to be secured. Compulsory licencing mechanisms as proposed by WHO, World Trade Organization (WTO) and World Intellectual Property Organization (WIPO)
External environment	Low production capacity worldwide	H	H	Advance purchase agreements with broad list of producers will be secured including collaboration agreements with generic producers in third countries will be deployed Investment loans from International Finance Institutions (IFIs).
External environment	Production scale up is hindered by IP abuse	M	M	COVAX is negotiating licencing agreement with some manufactures already. In addition, in May 2020 WHO launched the COVID-19 Technology Access Pool (C-TAP).
External environment	Conflict-affected areas that are hard to reach or where there is no presence of the national authorities	M	L	Collaboration with aid organisations (UN Agencies, Red Cross and Red Crescent, INGO)
People and the organisation	Non repayment of the loan due to lack of pledges	L	L	Selection of GAVI as borrower – it has 100% converting rate for turning pledges to payments
External environment	Risk aversion of private sector and financial institutions limiting investments in health and the pharmaceutical	M	H	Close collaboration and coordination with other initiatives providing support to the supply and regulatory dimension such as the Team Europe initiative MAV+ and transparent communication around AVMA.

	sector.			
External environment	Insufficient capacity of African National Regulatory Authorities (NRAs) to ensure the Maturity Levels necessary for oversight of manufacture of Prequalified vaccine;	M	H	Close collaboration and coordination with other initiatives to ensure that the needed regulatory environment is in place.
External environment	Lack of demand for the vaccines produced	M	M	GAVI will continue to work with the AU and Member States on demand solidarity.
People and the organisation	Countries may have insufficient Expanded Programme of Immunisation (EPI) team capacity and capabilities to maintain, restore and strengthen immunisation programmes and reach zero-dose communities	H	H	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.

Assumptions

- COVAX facility builds on Gavi's reputation and long term relations with vaccine producers;
- COVAX relies on guidelines and technical assistance from the World Health Organisation (WHO);
- Timely and adequate implementation of procurement procedures;
- Availability of staff and manageable turnover rates in COVAX facility;
- Effective coordination with partner governments and with all implementing partners, including aid organisations;
- Partner governments take full responsibility and act to ensure deployment of delivered vaccines within their countries;
- Targeted populations accept to be vaccinated.
- The success of AVMA will rely on concerted action from wider stakeholders at local, regional, and global levels, to create the necessary regulatory, policy environment, investment, technology transfers, and demand required to build a sustainable vaccine industry.

- African manufacturers have access to the necessary financial resources to invest in vaccine manufacturing capacity.
- Technology and know-how transfer is assured.

3.5 THE INTERVENTION LOGIC (Modified to reflect the expanded scope of the action in support to AVMA and the GAVI core actions)

This EU contribution to COVAX and AVMA Advance Market Commitments (AMC) and to global immunisation efforts is a €300 million EU grant to Gavi, which will be complemented by €200 million in EU budgetary guarantees to cover an EIB loan to Gavi. For this purpose, 400 000 000 EUR will be used from the Neighbourhood, Development and International Cooperation Instrument – Global Europe. Appropriations will come from the Global Challenges programme for the grant part and the relevant provisioning line of NDICI Global Europe for the budgetary guarantees.

For COVAX to conclude purchase agreements with manufacturers it needs to show strong financial backing – hence, the grant complemented with the EFSD+ guaranteed EIB loan will ensure bridge-financing of donor pledges before these are turned into payments.

Through COVAX this support package will:

- Strengthen the financial capacity and negotiation power of the COVAX facility to enter into favourable advance purchase agreements with vaccine manufacturers, which will result in early access and favourable vaccine prices for all countries participating in the COVAX facility.
- Provide a substantial number of future vaccines for eligible countries under the COVAX AMC. As the EU contribution is a part of a broader and joint donor effort, and allocations to countries are based on population size, the EU contribution will benefit notionally all AMC countries. The number of vaccines procured will depend on the eventual price per dose that can be secured by COVAX in negotiations with manufacturers. The average price is expected to be USD 7 for AMC countries.
- Reduce or remove financing constraints and bottlenecks for access to vaccines in low-income countries. It is expected to ensure equitable global access to vaccines by supporting eligible countries' under the NDICI Regulation in their efforts to procure them.

Through AVMA this support package will:

- incentivise market players to bring forward investments, while not disrupting or undermining the competitive Gavi/UNICEF tender process.
- make investments in African vaccine manufacturers commercially viable, enabling them to bid at competitive global prices as they achieve economies of scale.
- Promote diversification of vaccine platform technologies and increase vaccine production capacities.

Through the global immunisation efforts this support package will:

- contribute towards the Gavi 6.0 programme for 2026-2030, that is Gavi's core business, specifically the pillar to introduce and scale up vaccination coverage.
- Ensure the delivery of life saving vaccines to lower-middle income countries to increase coverage and equitable use of Gavi eligible vaccines.
- Strengthen health systems in beneficiary countries for integrated and resilient primary health care services.

These 3 support packages together will lead to an increased availability of essential vaccines in the immediate (COVAX and GAVI core) and in the longer term (AVMA) for GAVI eligible countries as well as an improved vaccine-led pandemic response capacity and therefore result in more equitable access and utilisation of life saving vaccines and reduce vaccine preventable morbidity and mortality.

Objectively verifiable indicator will be used to assess the degree of achievement of the expected results and successful implementation of the activities. They are presented in the logical framework below.

For COVAX, in particular the number of doses of effective and safe COVID-19 vaccines provided to Ministries of Health in 92 COVAX AMC eligible countries⁹ will be monitored. Vaccines will be shipped and delivered to the MoH in the concerned countries according to the shipment plan of UNICEF Supply Division or Pan American Health Organization (PAHO). Vaccines will be stored and then distributed nationwide by the MoH in the respective countries. Countries will report back to Gavi on numbers of vaccines received and people vaccinated.

If the COVAX AMC is not adequately funded, AMC eligible economies are likely to face three-four years delay in receiving COVID-19 vaccines. AMC eligible economies will be asked to share the costs of the COVID-19 vaccine programme by contributing either to the costs of the vaccines or for delivering them to the population. However, if countries face financial constraints, it will be ensured that this will not block their access to the vaccines.

In the case of AVMA, indicators will focus on the WHO pre-qualification of locally produced vaccines, procurement of GAVI eligible vaccines from African manufacturers and the availability of drug substance platform technologies.

Indicators for GAVI core are number of people vaccinated and vaccine coverage.

⁹ **Low income:** Afghanistan, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Dem. Rep., Eritrea, Ethiopia, Gambia, The Guinea, Guinea-Bissau, Haiti, Korea, Dem. People's Rep., Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Niger, Rwanda, Sierra Leone, Somalia, South Sudan, Syrian Arab Republic, Tajikistan, Tanzania, Togo, Uganda, Yemen, Rep.,

Lower-middle income: Angola, Algeria, Bangladesh, Bhutan, Bolivia, Cabo Verde, Cambodia, Cameroon, Comoros, Congo, Rep. Côte d'Ivoire, Djibouti, Egypt, Arab Rep., El Salvador, Eswatini, Ghana, Honduras, India, Indonesia, Kenya, Kiribati, Kyrgyz Republic, Lao PDR, Lesotho, Mauritania, Micronesia, Fed. Sts., Moldova, Mongolia, Morocco, Myanmar, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, São Tomé and Príncipe, Senegal, Solomon Islands, Sri Lanka, Sudan, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Vietnam, Palestine* and Gaza, Zambia, Zimbabwe

Additional IDA eligible: Dominica, Fiji, Grenada, Guyana, Kosovo*, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga, Tuvalu.

* "This designation shall not be construed as recognition of a State of Palestine and is without prejudice to the individual positions of the Member States on this issue."

* "This designation is without prejudice to positions on status and is in line with UNSC 1244 and the ICJ Opinion on the Kosovo declaration of independence."

3.6 LOGICAL FRAMEWORK MATRIX

The indicative logframe matrix will evolve during the lifetime of the Intervention. The activities, the expected outputs and related indicators are indicative and may be updated during the implementation of the Intervention as agreed by the parties (the European Commission and the implementing partner/s).

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

Results	Results chain (e): Main expected results (maximum 10)	Indicators (e): (at least one indicator per expected result)	Baselines (values and years)	Targets (values and years)	Sources of data	Assumptions
Impact	To mitigate the social and economic impact of COVID-19 and to reduce morbidity and mortality of vaccine preventable diseases in the low and lower-middle income countries.	1. UN Human Development Index (HDI)	1 to be determined (TBD)	1 TBD	1. UN Human Development Index (HDI)	<i>Not applicable</i>
Outcome 1	1. Vaccines purchased through the EU-funded intervention are administered in AMC eligible countries, especially to priority groups identified (e.g. healthcare workers, elderly, vulnerable and high-risk people)	1.1 Number of vaccines administered (disaggregated by country, vulnerable groups targeted, sex, urban/rural)	1.1 0	1.1 1,8 billion	1.1 GAVI /COVAX reports 1.2 UNICEF report	Eligible countries participate in COVAX Facility
Outcome 2	Strengthened vaccine manufacturing capacity in Africa.	2.1 Number of African vaccine manufacturers operating sustainably 2.2 Maximum drug product capacity of the AVMA-supported supply base	2.1 0 2.2 0	2.1 4 2.2 0.7 billion doses	GAVI/AVMA reports	African manufacturers have access to investments

Outcome 3	Improved immunisation coverage of GAVI eligible vaccines.	3.1 Breadth of protection 3.2 Vaccine coverage disaggregated by antigen	Tbd ¹⁰	Tbd	WHO/UNICEF Estimates of Immunisation Coverage; Country Health Information System	Continued stable supply of vaccines from manufacturers Country applications approved by Gavi
Output 1 related to Outcome 1	1.1 COVID-19 vaccines are procured for AMC countries	1.1.1 Number of vaccine doses procured per country	1.1.1 0	1.1.1 at least 20% of country population	1.1 GAVI /COVAX reports 1.2 UNICEF report	Vaccines supply sufficient to deliver required doses
Output 1 related to Outcome 2	2.1 GAVI eligible vaccines purchased from African vaccine manufacturers.	2.1.1 Number of African manufacturers achieved WHO pre-qualification. 2.1.2 Number of manufacturers supported by AVMA having secured at least one UNICEF tender.	2.1.1 0 2.1.2 0	2.1.1 Tbd 2.1.2 4	GAVI/AVMA report	African manufacturers have access to investments; Incentive payments are well calibrated
Output 2 related to Outcome 2	2.2 Drug substance platform technologies established on the African continent.	2.2.1 Number of drug substance platform technologies established	2.2.1 0	2.2.1 3	GAVI/AVMA report	African manufacturers have access to investments; Incentive payments are well calibrated

¹⁰ Baselines and targets will align with those included in the Measurement Framework for the Gavi 6.0 strategy being developed. These will be approved by the Gavi board.

Output 1 related to Outcome 3	3.1 Children vaccinated with Gavi-supported vaccines	3.1 Number of children vaccinated disaggregated by antigen	Tbd ¹¹	Tbd	WHO/UNICEF Estimates of Immunisation Coverage; Country Health Information System	Continued stable supply of vaccines from manufacturers Country applications approved by Gavi Adequate service delivery capacity of national governments
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¹¹ Baselines and targets will align with those included in the Measurement Framework for the Gavi 6.0 strategy being developed. These will be approved by the Gavi board.

4 IMPLEMENTATION ARRANGEMENTS

4.1 FINANCING AGREEMENT

In order to implement this action, it is not foreseen to conclude a financing agreement with the 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 156 months from the date of the adoption by the Commission of this Financing Decision.

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

4.3 IMPLEMENTATION MODALITIES

The Commission will ensure that the EU appropriate rules and procedures for providing financing to third parties are respected, including review procedures, where appropriate, and compliance of the action with EU restrictive measures¹².

The action will be implemented through direct management for the grant component and via indirect management for the guarantee part.

4.3.1 Direct management (grants)

(a) Purpose of the grant

The overall objective of this action is to mitigate the social and economic impact of COVID-19 in the low and lower-middles income countries and to reduce morbidity and mortality of vaccine preventable diseases.. The action will implement EU's solidarity support to these countries and help prevent the transmission of COVID-19 and other vaccine preventable diseases around the world. The expected main output of the action is that a number of future COVID-19 vaccines will be procured for COVAX AMC countries, Number of children immunised and number of manufacturers with WHO pre-qualification. As stated in section 1.5, all countries participating in the COVAX Facility will ultimately benefit from this joint mechanism.

Indicative activities include: advance purchase agreements and upfront investment in manufacturing capacities, so that vaccines can be produced at scale as soon as they are proven successful, safe and efficient; obtainment and transfer of a number of options for a future vaccine to COVAX AMC countries; reserve of doses for eligible economies; pooling procurement; enhanced purchasing power to achieve sufficient volumes at acceptable prices; sharing the risks associated with vaccine development.

¹² 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.

(b) 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 Vaccine Alliance, which is the legal representative of the COVAX Facility, in accordance with article 195 (c) of Regulation (EU) 2018/1046, because the beneficiary is a de facto monopoly:

- Gavi has the Office of the COVAX Facility to oversee administration and coordination of the Facility. The COVAX Facility is the central global facility for joint procurement of future vaccines. Gavi is a global health initiative in the immunisation field, which works as a public-private partnership. 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 USD 1.5 billion per year on purchasing and delivering regular vaccines to the 73 poorest countries, all of which AMC countries.
- COVAX is the vaccines pillar of ACT Accelerator, which is co-led by CEPI, Gavi and WHO – working in partnership with developed and developing country vaccine manufacturers, UNICEF, the World Bank, civil society organisations and others. COVAX is the only global initiative that is working with governments and manufacturers to ensure COVID-19 vaccines are available worldwide to economies of all financial means. The ACT Accelerator Framework as global coordination mechanism for developing and deploying new therapeutics, diagnostics, and vaccines against COVID19 has been set up at the initiative and the strong support of the European Commission.

(c) Exception to the non retroactivity of costs

The Commission authorises that the costs incurred may be recognised as eligible as of 1 March 2021 for the following reason: this grant addresses an extreme and urgent situation due to the COVID-19 pandemic.

The costs incurred may be recognised as eligible as of 1 March 2021, which is the first date of the full month, following the political announcement of this EU contribution: at the G7 virtual leaders' meeting of 19 February 2021, President Ursula von der Leyen announced an additional EUR 500 million for the COVAX Facility, doubling the EU contribution up to EUR 1 billion, with new EUR 300 million in grant and EUR 200 million EIB loan. This will allow Gavi to finance the advance purchase agreements that were necessary to be secured as early as possible based on the high level pledges made.

4.3.2 EFSD+ operations covered by budgetary guarantees

Financing and investment operations supported by budgetary guarantees may be implemented under indirect management with the European Investment Bank (EIB).

4.4 SCOPE OF GEOGRAPHICAL ELIGIBILITY FOR PROCUREMENT AND GRANTS

The geographical eligibility in terms of place of establishment for participating in 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.

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

4.5 INDICATIVE BUDGET

	EU contribution (amount in EUR)	Indicative third party contribution, in currency identified
Grants – direct management – cf. section 4.3.1	300 000 000	
Provisioning of EFSD+ CPF	100 000 000	
Evaluation, (cf. section 5.2), Audit (cf. section 5.3)/Expenditure verification	N.A. (will be covered by another decision)	N.A.
Communication and visibility (cf. section 6)	N.A.	
Contingencies	N.A.	
Total	400 000 000	

4.6 ORGANISATIONAL SET-UP AND RESPONSIBILITIES

Gavi is governed by an international Board consisting of 28 members, including government representatives from donor and recipient countries 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 Luxembourg.

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. 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 Commission regularly engages with the decisions of Gavi through the Board and as such will be abreast of key issues in the progress of vaccine programmes, including those on which this action focuses.

The COVAX Facility is being established within the COVAX Pillar of the ACT-Accelerator. As Gavi is the legal entity administering the COVAX Facility and AVMA, the governance arrangements will build on the Gavi Board and its Committees, with new bodies established to ensure appropriate oversight and agility to support the functioning of the Facility.

Gavi manages the COVAX Facility and AVMA and acts as the borrower of the EIB loan covered by the EFSD+ Guarantee. Gavi organises pledging conferences to raise funds through donations from

countries, foundations, wealthy individuals, etc. It administers the necessary contract and financial management, turning pledges into cash.

The Office of the COVAX Facility is being established within the Gavi Secretariat to ensure a dedicated team to support the Facility operations. The Office comprises of several dedicated teams: e.g. design and operations; deal making and vaccine portfolio management; country engagement; and finance. The Office will also leverage dedicated, incremental resources within existing Gavi Secretariat teams (e.g. Resource Mobilisation, Legal, Public Policy Engagement, Governance and other teams).

The COVAX Facility Governance Bodies include: 1) COVAX Shareholders Council (self-financing economies); 2) COVAX AMC Engagement Group (AMC-eligible countries); 3) COVAX AMC Stakeholders Group; 4) COVAX Consensus Group. Also, technical groups, such as the Independent Product Group or the Procurement Reference Group.

The Facility will apply the WHO Allocation Framework as the basis for vaccine allocation decisions for Facility Participants, operationalised through the Allocation Mechanism. The Allocation Mechanism will comprise the Joint Allocation Taskforce and the Independent Allocation Validation Group.

The key decisions regarding COVAX and AVMA operations and financing will remain with the Gavi Board where the EU and the Commission are well represented. The Commission will work through the Gavi Board to ensure the proper operation of COVAX Facility and AVMA and equitable vaccine distribution in AMC countries. The Commission currently is part of a constituency shared with France, Germany, Ireland, Luxemburg.

The proposed EU package of EUR 500 million in grants and guaranteed loans is structured in the following way: one part of EUR 300 million is immediate cash through the NDICI grant, and another part of EUR 200 million is further bridge-financing through an EIB loan under EFSD + Guarantee. For this purpose 100 000 000 EUR is paid to the Common Provisioning Fund to guarantee the risk of the loan. For COVAX to conclude purchase agreements with manufacturers it needs to show strong financial backing – hence the grant complemented with the EFSD+ guaranteed EIB loan.

As part of its prerogative of budget implementation and to safeguard the financial interests of the Union, the Commission may participate in the above governance structures set up for governing the implementation of the action.

5 PERFORMANCE MEASUREMENT

5.1 MONITORING AND REPORTING

Performance measurement will be based on the intervention logic and the Logframe matrix, including its indicators.

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.

Reports shall be laid out in such a way as to allow monitoring of the means envisaged and employed and of the budget details for the action. The final report, narrative and financial, will cover the entire period of the action implementation.

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).

5.2 EVALUATION

Having regard to the nature of the action, a final evaluation will not be carried out for this action or its components.

The Commission may, during implementation, decide to undertake such an evaluation for duly justified reasons either on its own decision or on the initiative of the partner.

The evaluation reports shall be shared with the partner country and other key stakeholders. The implementing partner and the Commission shall analyse the conclusions and recommendations of the evaluations and, where appropriate, in agreement with the partner country, jointly decide on the follow-up actions to be taken and any adjustments necessary, including, if indicated, the reorientation of the project.

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 audits or expenditure verification assignments for one or several contracts or agreements.

The financing of the evaluation shall be covered by another measure constituting a financing decision.

5.3 AUDIT AND VERIFICATION

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 audits or expenditure verification assignments for one or several contracts or agreements.

The financing of the audit shall be covered by another measure constituting a financing decision.

6 COMMUNICATION AND VISIBILITY

Communication and visibility is a contractual obligation for all entities implementing EU-funded external actions to advertise the European Union's support for their work to the relevant audiences.

To that end they must comply with the instructions given in the Communication and Visibility Requirements of 2018 (or any successor document), notably with regard to the use of the EU emblem and the elaboration of a dedicated communication and visibility plan, to be completed for every action at the start of implementation.

These obligations apply equally, regardless of whether the actions concerned are implemented by the Commission, the partner country (for instance, concerning the reforms supported through budget support), contractors, grant beneficiaries or entrusted entities. In each case, a reference to the relevant

contractual obligations must be included in the respective financing agreement, procurement and grant contracts, and delegation agreements.

In this particular action, the implementation of communication activities shall be the responsibility of the implementing partner and may be funded from the amounts allocated to the action. For the purpose of enhancing the visibility of the EU and its contribution to this action, the Commission may sign or enter into joint declarations or statements, as part of its prerogative of budget implementation and to safeguard the financial interests of the Union. Visibility and communication measures should also promote transparency and accountability on the use of funds.

Implementing partners shall keep the Commission and concerned EU Delegation/Office fully informed of the planning and implementation of specific visibility and communication activities before work starts. Implementing partners will ensure adequate visibility of EU financing and will report on visibility and communication actions as well as the results of the overall action to the relevant monitoring committees. The Commission, and where applicable, the relevant EU Delegation(s) will be consulted in advance on the planned communication activities around key milestones as well as on country-specific EU visibility and communication activities before work starts, in order to ensure greater outreach and impact.

The implementing partners shall provide any information requested by the concerned Delegations as input to their own communication activities, including by giving full access to relevant audio, photo and video material. The implementing partners shall coordinate communication activities with regional and bilateral communication initiatives funded by the European Union, to the extent possible. To enhance the effectiveness of communication activities, the implementing partners shall nominate contacts points responsible for communication. Monitoring and reporting of the activities will be provided on a regular basis.