



EN

THIS ACTION IS FUNDED BY THE EUROPEAN UNION

ANNEX

of the Commission Implementing Decision on the financing of the special measure in favour of contributing to the global immunisation efforts against the COVID-19 in low and lower-middle income countries for 2021

Action Document for ‘Contribution to the global immunisation efforts against the COVID-19 in low and lower-middle income countries’

SPECIAL MEASURE

This document constitutes the annual work programme in the sense of Article 110 of the Financial Regulation, and action plans/measures in the sense of Article 23 (4) of NDICI-Global Europe Regulation.

1 SYNOPSIS

1.1 Action Summary Table

1. Title CRIS/OPSYS business reference Basic Act	Contribution to the global immunisation efforts against the COVID-19 in low and lower-middle income countries CRIS number: NDICI CHALLENGE/2021/043-684 Financed under the Neighbourhood, Development and International Cooperation Instrument (<u>NDICI</u>)-Global Europe
2. Team Europe Initiative	This action does not contribute to Team Europe Initiative.
3. Zone benefiting from the action	. Direct beneficiaries: The action will target low and lower-middle income countries with the least population vaccination coverage for COVID-19 vaccines.
4. Programming document	NA
5. Link with relevant MIP(s) objectives / expected results	NA
PRIORITY AREAS AND SECTOR INFORMATION	
6. Priority Area(s), sectors	Human and social development
7. Sustainable Development Goals (SDGs)	Main SDG (1 only): <ul style="list-style-type: none">• SDG 3: Good Health and Well-being Other significant SDGs (up to 9) and where appropriate, targets: <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: 12264 - COVID-19 control – 100%			
8 b) Main Delivery Channel	<i>a) private sector institution – 60000 and</i> <i>b) Gavi, the Vaccine Alliance – 47122 and other multilateral organisations - 40000</i>			
9. Targets	<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			
10. Markers (from 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 and child health	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Disaster Risk Reduction @	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Inclusion of persons with Disabilities @	<input type="checkbox"/>	<input checked="" 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	<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"/>

	digital services		<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 checked="" type="checkbox"/>	<input type="checkbox"/>
	Covid-19	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
BUDGET INFORMATION				
12. Amounts concerned	Budget line: 14.020240 (Global Challenges – People) Total estimated cost: EUR 900 000 000 Total amount of EU budget contribution EUR 900 000 000.			
MANAGEMENT AND IMPLEMENTATION				
13. Type of financing	Direct management through: - Procurement - Grants Indirect management			

1.2 Summary of the Action

The COVID-19 pandemic has forced the global community to craft collective solutions and develop partnerships on a scale not seen before. Despite the successful development of vaccines, multilateral vaccines procurement and distribution mechanism put in place (COVAX) with considerable Team Europe support, and EU vaccines sharing gathering pace, the availability of vaccines and coverage of population in different places of the world is very uneven. The poorest countries being most underserved. This will likely lead to differences in the ability of countries to recover from this crisis and increase inequalities.

The State of the Union speech of September 2021 underlined that the first and most urgent EU priority was to speed up global vaccination. It stressed that less than 1 % global doses had administered in low income countries and announced that the Commission will add a donation of 200 million doses by mid next year.

Preventing the spread of COVID-19 infection through vaccination is a proven and the most cost-effective public health intervention. The primary objective of the action is to address the immediate public health needs of the low and lower-middle income countries to increase their population immunisation coverage in short term.

The objective will be achieved through the provision and delivery of 200 million COVID-19 vaccine doses to low and lower-middle income countries.

2 RATIONALE

2.1 Context

The COVID-19 pandemic has forced the global community to craft collective solutions and develop partnerships on a scale not seen before. Despite the successful development of vaccines, multilateral vaccines procurement and distribution mechanism put in place (COVAX) with considerable Team Europe support, and EU vaccines sharing gathering pace, the availability of vaccines and coverage of population in different places of the world is very uneven. The poorest countries being most underserved. This will likely lead to differences in the ability of countries to recover from this crisis and increase inequalities.

The new World Health Organization (WHO) Strategy to Achieve Global Covid-19 Vaccination by mid-2022 launched in October 2021 sets the targets to vaccinate 40% of the population of all countries by the end-2021 and 70% by mid-2022. However, 56 countries had not been able to vaccinate even 10% of the population by the end of September, the vast majority of these are countries in Africa and the Middle East.

The State of the Union speech (SOTEU) of September 2021 underlined that the first and most urgent EU priority was to speed up global vaccination. It stressed that less than 1 % global doses had administered in low income countries and announced that the Commission will add a donation of 200 million doses by mid next year.

Low vaccination rates in particular in Africa represents a major issue ahead of the AU-EU summit. This action will demonstrate further EU solidarity with partner countries suffering from COVID-19 pandemic and will ensure an important contribution to the equity in the global access to vaccines.

There are currently four European Medicines Agency (EMA) approved safe and effective COVID-19 vaccines (produced by Pfizer/Biontech, AstraZeneca, Moderna and Johnson&Johnson/Janssen) with a World Health Organisation (WHO) Emergency Use Listing Procedure (EUL) approval granted. They are used all across the globe and distributed also by the COVAX, which is a vaccines pillar of the ACT- Accelerator. Among these vaccines, mRNA vaccines have demonstrated particularly **high effectiveness to prevent severe disease**, death but also symptomatic disease and transmission. According to the latest scientific information available, their effectiveness after two doses seems to be maintained longer than other vaccines. This is particularly relevant in view of new variants like Omicron for which coverage is not yet known. In addition, mRNA vaccines are non-infectious: they do not contain infectious agents but solely the necessary information for the production of viral proteins. Therefore, **production of mRNA vaccine is safe** and does not rely on live organisms (such as cells cultures or egg cells), simplifying the manufacturing process. Compared to other vaccine types, **mRNA vaccine production can be scaled up more quickly**. The manufacturing is sequence-independent making it **highly adaptable to new variants**. The **producers of mRNA vaccines have largely complied with delivery schedules** to the EU, while those of other vaccine types had challenges and delays to the initially agreed delivery timelines. According to research by the Duke Global Health Innovation Center, for 2022, Pfizer/Biontech projects to expand production from 3 billion doses to 4 billion doses and Moderna from 0.8 billion doses to 3 billion doses ¹. Increasing the supply of actually delivered doses in 2022 to the least covered countries would improve the global situation and perception of access to vaccines equity. The COVAX Facility, by applying already functioning fair allocation mechanism developed by WHO and delivery logistics infrastructure, will be instrumental in the vaccines distribution. It is in the interest of the EU to prevent the spread of the virus and the emergence of new variants.

2.2 Problem Analysis

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

¹ <https://launchandscalefaster.org/covid-19/vaccinemanufacturing>

equitable access to COVID-19 vaccines for all countries.

In addition, on 19 January, the Commission adopted a Communication "A united front to beat COVID-19". It proposed to set up an EU vaccine sharing mechanism to help share part of doses already secured by the EU for own needs. The Team Europe approach aims at donating at least 500 million doses of vaccines to low and middle-income countries until the end of the year 2021, in particular through COVAX.

Gavi, the Vaccine Alliance (Gavi) is the legal entity administering the COVAX Facility, and works together with the Coalition for Epidemic Preparedness Innovations (CEPI) and WHO for this pillar. COVAX funds the development and manufacturing of vaccines, raises donor funding for the procurement and deployment of COVID-19 vaccines in a fair and equitable manner, and procures vaccines at low cost for 92 low- and lower-middle income countries and humanitarian actors (eligible for COVAX Advance Market Commitment (AMC) financing instrument support) and other self-financing participants.

The initial COVAX goal was to secure and deliver 2 billion vaccines doses by the end of 2021, including 1.3 billion vaccine doses for 92 low and middle-income countries. However due to global supply issues (including export restrictions put by some countries), limited manufacturing capacity of safe and effective vaccines and high competition on the vaccines purchase market, the latter goal was reduced to around 1 billion doses, allowing vaccinated population coverage in 92 AMC countries to only reach 20%.

In 2021 COVAX AMC has raised USD 10 billion in donations, of which the EU provides EUR 400 million (the whole Team Europe provides EUR 2.9 billion) in grants and EUR 600 million in guarantees (EFSD/EFSD+ provided to the European Investment Bank), and secured access to a diverse portfolio of 1.7 billion doses through direct procurement. Of these, however, only 340 million doses have been delivered to 86 AMC countries by end October 2021. More than 40% of COVAX deliveries to beneficiary countries at this point are provided by donations of countries that share their surplus doses, secured through their own contracts with vaccines manufacturers.

There is an urgent need to improve significantly the actual vaccines flow to low income countries, coordinated and aligned with on-going international initiatives, and profiting from a fair allocation mechanism for COVID-19 vaccines distribution designed by WHO and implemented through the COVAX Facility.

The commitment announced by the President Von der Leyen in the SOTEU 2021 will complement the on-going efforts and ensure effective and rapid 200 million doses distribution, contributing to the Team Europe's goal of delivering 500 million doses by middle 2022.

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

The populations of low income countries with the lowest immunisation rates that are also eligible to COVAX AMC support 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 or other suitable entity as distributor of COVID-19 vaccines will also be important in advising and supporting the authorities on the further deployment of vaccines within their countries.

3 DESCRIPTION OF THE ACTION

3.1 Objectives and Expected Outputs

The Overall Objective (Impact) of this action is to address the immediate public health needs of the low and lower-middle income countries to increase their population immunisation coverage in short term.

The Specific Objective is to secure and support the distribution of 200 million COVID-19 vaccine doses to countries in need.

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

- 1.) 200 million doses of safe and effective COVID-19 vaccines approved by EMA are secured by middle 2022
- 2.) 200 million doses are distributed to low and lower-middle income countries with the lowest immunisation coverage among those eligible to COVAX AMC support

3.2 Indicative Activities

Activities related to Output 1

- Securing 200 million doses of COVID-19 vaccines for countries with lowest vaccination rates
- Conducting a procurement procedure with COVID-19 vaccines manufactures for 200 million mRNA vaccine doses and related ancillaries – syringes, diluents etc.
- Transmitting procured vaccines to COVAX Facility or other suitable entity for distribution to eligible beneficiaries

Activities related to Output 2:

- Applying WHO approved allocation mechanism to identify eligible beneficiaries
- Distributing vaccines and ancillaries to eligible beneficiaries

3.3 Mainstreaming

Environmental Protection & Climate Change

NA

Gender equality and empowerment of women and girls

As per OECD Gender DAC codes identified in section 1.1, this action is labelled as G1. This implies that 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.

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.

Disability

As per OECD Disability DAC codes identified in section 1.1, this action as D1. Persons with disabilities and pre-existing conditions (particularly girls, women and elderly) may be at greater risk due to inaccessible information about COVID-19 vaccination and may experience barriers to accessing health services, and will be addressed by this action.

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.

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.

Other considerations if relevant

Human health is a fundamental value and an investment in economic growth and social cohesion. Healthy individuals are more likely to be employed and less likely to be socially excluded. A healthy workforce is more productive, and healthcare services and health industries (pharmaceuticals, medical devices, and health research) are an important knowledge-intensive economic sector that enables people to maintain and improve their health and creates a steady demand for workers.

3.4 Risks and Lessons Learnt

Category	Risks	Likelihood (High/ Medium/ Low)	Impact (High/ Medium/ Low)	Mitigating measures
People and organisation	Not meeting the envisaged delivery mid-2022 (required duration of the procedure is 9-12 months)	H	H	Streamline procurement procedure to mitigate delays.
External environment	Procuring the vaccines may imply the Commission acquires title over	H	H	The draft contract will need to ensure that the title of the vaccines is not transferred to the Commission.

	those vaccines and liability relating to those vaccines will pass onto the Commission.			
External environment	The manufacturers may not respond to an unattractive call for tender for mRNA vaccines	H	H	Other EMA approved vaccines are available at lower price, therefore the procedure could be opened to all EMA approved vaccines. Given that the final beneficiaries of vaccines are low and lower-middle income countries, direct negotiations with manufactures would be needed to agree on a preferential price, distribution conditions, including places etc. but these are not foreseen under open or restricted procurement procedures
External environment	Unsuccessful tenderers may challenge process leading to delays in conclusion of procurement and eventual court ordered suspension of the procedure	H	H	To open the the procurement procedure to all EMA-approved vaccines
External environment	Successful tenderers may not deliver the vaccines according to the agreed schedule, including due to complexity of procedure	M	H	Foresee penalties/counter measures in the procurement contract
External environment	Disconnect between the supply contracts with the manufacturer on the one hand and the distribution with Gavi or another suitable entity on the other hand	M	H	Coordinate well with both entities.
External environment	Partner countries face difficulties in rolling out mRNA vaccines requiring	M	M	To ensure the inclusion of a requirement for vaccines to be suitable for rollout in poor settings in the tendering documents

	ultra cold chain and some doses remain unused, particularly if the type of vaccine procured is not suited to the context of low-income countries			
Lessons Learnt: Unforeseen epidemiological situation changes can provoke export restrictions in vaccine manufacturing countries, so a mix of vaccines from several producers with a large productions capacity is important. .				

3.5 The Intervention Logic

The underlying intervention logic for this action is that EU will be providing an additional 200 million doses to low and lower-middle income countries, and contributing as such to the announced commitment of Team Europe to share 500 million doses by middle 2022 with countries in need.

The purchase of these mRNA vaccines will be managed directly by the Commission through a procurement procedure and distributed by Gavi through the COVAX Facility or by another suitable entity.

3.6 Logical Framework Matrix

This indicative logframe constitutes the basis for the monitoring, reporting and evaluation of the intervention.

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

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

The indicative logical framework matrix may evolve during the lifetime of the action depending on the different implementation modalities of this action.

The activities, the expected Outputs and related indicators, targets and baselines included in the logframe matrix may be updated during the implementation of the action, no amendment being required to the Financing Decision.

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

Results	Results chain (@): Main expected results (maximum 10)	Indicators (@): (at least one indicator per expected result)	Baselines (values and years)	Targets (values and years)	Sources of data	Assumptions
Impact	To address the immediate public health needs of the low and lower-middle income countries to increase their population immunisation coverage in short term	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. 200 million of COVID-19 vaccine doses are purchased	1.1 Number of procurement contract signed	1.1 0	1.1 at least 1	1.1 Procurement contract signed	
Outcome 2	2. 200 million of COVID-19 vaccine doses are delivered to countries in need	2.1 Number of vaccines delivered (disaggregated by country, vulnerable groups targeted, sex, urban/rural)	2.1 0	2.1 200 million doses	2.1 Gavi /COVAX or other suitable entity reports 2.2 UNICEF report	Vaccines supply sufficient to deliver required doses
Output 1 related to Outcome 1	1.1 200 million doses of safe and effective COVID-19 vaccines approved by EMA are procured by middle 2022	1.1.1 Number of vaccine doses procured per vaccine type	1.1.1 0	1.1.1 200 million doses	1.1 Procurement contract signed	

Output 1 related to Outcome 2	2.1 200 million doses are distributed to low and lower-middle income countries with the lowest immunisation coverage among those eligible to COVAX AMC support	2.1.1 Number of beneficiary countries	2.1.1 0	2.1.1 at least 20 with lowest global immunisation rates	2.1. Gavi /COVAX or other suitable entity reports 2.2 UNICEF report	Vaccines supply sufficient to deliver required doses
--	--	---------------------------------------	---------	---	--	--

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

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

4.3 Implementation Modalities

The Commission will ensure that the EU appropriate rules and procedures for providing financing to third parties are respected, including review procedures, where appropriate, and compliance of the action with EU restrictive measures.²

4.3.1 Direct Management (Procurement)

Procurement will be used to achieve the Specific Objective through securing and supporting the distribution of 200 million COVID-19 mRNA vaccine doses to countries in need.

A service contract a suitable entity could be envisaged for the distribution of the doses.

4.3.2 Direct Management (Grants)

Should a service contract with a suitable entity for the delivery of the vaccine doses not be feasible, this part of the action may be implemented under direct management through the award of a grant to an entity with a proven track record of vaccine distribution.

4.3.3 Changes from direct to indirect management mode and vice-versa

If circumstances require, a pillar-assessed entity with a proven track record of vaccine distribution could also be chosen under indirect management,.

² www.sanctionsmap.eu. 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, the OJ prevails.

4.4 Scope of geographical eligibility for procurement and grants

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

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

Indicative Budget component	EU contribution (amount in EUR)		
Implementation modalities – cf. section 4.3³			
Procurement (direct management) – cf. section 4.3.1	900 000 000	800 000 000	
Grants (direct management) – cf. section 4.3.2		100 000 000	
Evaluation – cf. section 5.2 Audit – cf. section 5.3	will be covered by another Decision		
Totals	900 000 000	900 000 000	900 000 000

4.6 Organisational Set-up and Responsibilities

For the procurement directly managed by the Commission, applicable rules of chosen procedure will apply.

Subsequent transfer of procured vaccines for the distribution in beneficiary countries will be defined in the service contract or direct grant to Gavi or any other suitable entity.

For the distribution part, COVAX or another suitable entity would need to 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.

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

5 PERFORMANCE MEASUREMENT

5.1 Monitoring and Reporting

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

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

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 following the best practice of evaluation dissemination. 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.

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.

It will remain a contractual obligation for all entities implementing EU-funded external actions to inform the relevant audiences of the Union's support for their work by displaying the EU emblem and a short funding statement as appropriate on all communication materials related to the actions concerned. This obligation will continue to apply equally, regardless of whether the actions concerned are implemented by the Commission, partner countries, service providers, grant beneficiaries or entrusted or delegated entities such as UN agencies, international financial institutions and agencies of EU member states.

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

Appendix 1 REPORTING IN OPSYS

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

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

The present Action identifies as

Action level		
<input checked="" type="checkbox"/>	Single action	Present action: all contracts in the present action
Group of actions level		
<input type="checkbox"/>	Group of actions	Actions reference (CRIS#/OPSYS#):
Contract level		
<input type="checkbox"/>	Single Contract 1	<foreseen individual legal commitment (or contract)>
<input type="checkbox"/>	Single Contract 2	<foreseen individual legal commitment (or contract)>
	(...)	
<input type="checkbox"/>	Group of contracts 1	<foreseen individual legal commitment (or contract) 1> <foreseen individual legal commitment (or contract) 2> <foreseen individual legal commitment (or contract) #>