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ANNEX 1

to the Commission Implementing Decision on the
financing of the multiannual action plan for the thematic programme on Global Challenges (People)
for 2022-2024

Action Document for : Support to global immunisation efforts through GAVI, the Vaccine Alliance

MULTIANNUAL

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

1 SYNOPSIS

1.1 Action Summary Table

1. Title CRIS/OPSYS business reference Basic Act	Support to global immunisation efforts through GAVI, the Vaccine Alliance CRIS number: ACT-61045 Financed under the Neighbourhood, Development and International Cooperation Instrument (<u>NDICI-Global Europe</u>)
2. Team Europe Initiative	No
3. Zone benefiting from the action	Global. The action shall be carried out in lower income countries eligible for Gavi's support.
4. Programming document	NDICI Global Challenges Multiannual Indicative Programme (MIP) 2021-2027
5. Link with relevant MIP(s) objectives / expected results	The action intends to contribute to Specific objective 1 (Health) of the People priority of the Global Challenges MIP and to the following results: <ul style="list-style-type: none">• Result 1: reinforced global initiatives, including support for global funds that are key enablers of universal health coverage, to improve financial risk protection and access to quality essential healthcare services and safe, effective, quality and affordable essential medicines and vaccines for all;• Result 3: accelerated progress towards universal access to basic health services, including immunisation and sexual and reproductive healthcare.
PRIORITY AREAS AND SECTOR INFORMATION	
6. Priority Area(s), sectors	Human and social development 12250 (Infectious Disease Control)

7. Sustainable Development Goals (SDGs)	Main SDG: SDG 3: Good Health and Well-being Other significant SDGs: SDG 1: No poverty SDG 5: Achieve gender equality and empower all women and girls SDG 10: Reduced inequalities SDG 13: Climate action SDG 17: Partnerships for the Goal			
8 a) DAC code(s)	Main DAC code: 12250 (Infectious Disease Control) – 100%			
8 b) Main Delivery Channel	Gavi, the Vaccine Alliance – 47122			
9. Targets	<input type="checkbox"/> Migration <input checked="" 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 type="checkbox"/>	<input checked="" type="checkbox"/>
	Disaster Risk Reduction	<input checked="" type="checkbox"/>	<input 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 type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	Climate change adaptation	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

11. Internal markers and Tags:	Policy objectives	Not targeted	Significant objective	Principal objective
	Digitalisation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	digital connectivity digital governance digital entrepreneurship digital skills/literacy digital services	YES <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	NO <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	
	Connectivity	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	digital connectivity energy transport health education and research	YES <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	NO <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	BUDGET INFORMATION			
12. Amounts concerned	Budget line(s) (article, item): 14.020240 – Global Challenges People Total estimated cost: EUR 10,5 billion (for 2021-2025) Total amount of EU budget contribution: EUR 300 million. The contribution is for an amount of EUR 150 million from the general budget of the European Union for 2023 and for an amount of EUR 150 million from the general budget of the European Union for 2024, subject to the availability of appropriations for the respective financial years following the adoption of the relevant annual budget, or as provided for in the system of provisional twelfths.			
MANAGEMENT AND IMPLEMENTATION				
13. Type of financing	Direct management through grants.			

1.2 Summary of the Action

The action aims to support the Vaccine Alliance's (Gavi)'s, vision of "Leaving no one behind with immunisation" and a mission to save lives and protect people's health by increasing equitable and sustainable use of vaccines. The EU is a long standing donor of this global initiative. The EUR 300 million pledge made by the EU in June 2020 will support the implementation of its five-year strategic programme for 2021-2025 - Gavi 5.0, to shape markets for vaccines, to ensure sustainable long run development outcomes, help support country health system

strengthening and resume immunisation programmes disrupted during the pandemic, and contribute to the prevention of epidemics through stockpiles for vaccines for yellow fever, meningitis, cholera and ebola.

2 RATIONALE

2.1 Context

Human development and health are at the core of our multilateral commitment towards achieving theSDG3 by 2030 and leaving no one behind. This means taking a human rights centred approach to guarantee that all individuals can be healthy and thrive and can have equal opportunities.

Engrained discriminations and inequalities, in all their senses, impede part of the population from exercising their rights, accessing basic services and contributing to their full potential, putting a break to sustainable development. Gender inequality in particular is one of the most persistent forms of inequality and barrier to human development; it has a multiplier effect in achieving poverty eradication. Investing in the human development is also investing in children and in youth, as key agents of development.

The COVID-19 pandemic has not only exacerbated existing social and economic inequalities, it has also reversed hard won gains when it comes to health. The pandemic has exposed the lack of global health security preparedness and significantly hindered progress on global health and in achieving SDG3. Essential health services are being interrupted, years of progress are reversed, for maternal and child health and nutrition, access to family planning, immunisation, non-communicable diseases and communicable diseases. Despite impressive progress on global health in the past 20 years, only 50% of the world's population has access to basic health care, while inequalities persist within and between countries. Health systems in many partner countries remain fragile, underfunded and confronted with deadly diseases.

Since its inception, Gavi has protected 888 million children in 77 countries through routine immunisation and contributed to the further immunisation of over 1 billion people through campaigns (not including COVID19 vaccination). With approximately 1.2 million future deaths prevented in 2020 alone, Gavi has helped lower-income countries to prevent more than 15 million future deaths through its support for routine immunisation programmes and vaccination campaigns since 2000.

Gavi routinely reaches more households than any other health service and brings communities into regular contact with the health system. This provides an effective platform to deliver other primary health care services – including nutrition counselling – and upon which to build universal health coverage. Support to Gavi is essential to cover for the delays and disruptions incurred in vaccination campaigns during the pandemic.

Gavi 5.0 aims to reach over 300 million more children with vaccines, saving 7–8 million lives that would otherwise be lost; accelerate the roll-out of the Human papillomavirus (HPV) vaccine to girls that protects against up to 70–90% of cervical cancer cases; provide the most comprehensive package of vaccination to supported countries, protecting against 18 diseases.

Vaccines save lives and have a long-lasting effect on societies and the environment. As a preventive intervention, immunisation averts significant future healthcare costs associated with the diseases prevented. Nevertheless, resource scarcity, environmental degradation and climate change are issues of concern because they disproportionately affect people in the countries that Gavi supports. At the same time, Gavi also aims to mitigate the adverse environmental impact of its programmes and operations. The development, production, procurement, delivery, and disposal of vaccines and related products incur their own environmental costs. To minimise these consequences, Gavi works with partners and countries to implement approaches that aim to reduce environmental impact.

As a public-private partnership, Gavi represents the sum of its partners individual strengths, from WHO's scientific expertise and UNICEF's procurement system to the financial know-how of the World Bank and the market knowledge of the vaccine industry. Gavi draws on the skills of a variety of partners, combining the technical expertise of the development community with the business know-how of the private sector. The Alliance's

immunisation work plays a critical role in strengthening primary health care (PHC), contributing to the Sustainable Development Goal (SDG) of Universal Health Coverage (UHC), ensuring that no one is left behind.

The European Union is a long-standing supporter of GAVI, and has contributed EUR 268 million from 2003 to 2020. In addition to the EUR 300 million from this action to support the GAVI 5.0 strategy, the European Union contributed to the Covax Facility, a specific mechanism set up for COVID-19 vaccination, with EUR 400 million in guarantees from the European Investment Bank, a EUR 200 million loan for the COVAX AMC¹ and of an additional EUR 400 million in grant funding to support the COVAX Facility to secure access to the future COVID-19 vaccine in low and middle-income countries.

2.2 Problem Analysis

Improved access to vaccines has changed the lives of millions of people in low-income countries. Since its inception, Gavi has protected a whole generation of children from potentially fatal infectious diseases. Gavi's support for an expanding portfolio of vaccines has been a major factor in reducing the number of deaths due to vaccine-preventable diseases by as much as 70% since 2000. The introduction of the rotavirus vaccine has emptied wards that used to be full of children suffering from acute and potentially fatal diarrhoea. New pneumonia vaccines are tackling one of the largest killers of children and preventing the spread of antimicrobial resistance (AMR). The Alliance owes this achievement to its unique capabilities in supporting countries to improve access to vaccines and strengthen immunisation delivery systems. In doing so, the Alliance focuses on country ownership and financial sustainability through its co-financing and transition model. It has also developed a powerful market shaping model for vaccines pooling demand from countries, accounting for almost 60% of the global birth cohort.

The Alliance's 2021-25 strategy ("Gavi 5.0") builds on these successes and aims to accelerate the journey towards universal immunisation. Immunisation already reaches more households than any other health intervention. Every child ought to receive a full package of vaccines and there is a real possibility that immunisation could be truly universal by 2030 – but achieving this requires an urgent acceleration of this journey. This would provide a strong platform for primary health care (PHC) as a pathway to universal health coverage (UHC) and the SDG vision of 'leaving no-one behind'.

Too many children are still missing out on the benefits of vaccination. The cumulative effects of population growth and displacement, climate change and increasing fragility, coupled with those of recurrent disease outbreaks, are threatening these hard-won gains. Each year 1,5 million people die from vaccine-preventable diseases. These deaths are entirely avoidable. Reaching those hard-to-reach communities that are still missing out on vaccination remains a huge challenge, one that is made more difficult by the pressures caused by conflict, country fragility and migration. Whether people are on the move because of climate change, war or urbanisation, or because they are part of nomadic communities, the result is the same. The congregation of large groups of displaced people, often underimmunised or even unimmunised, in cramped and crowded conditions creates the ideal conditions for outbreaks of dangerous diseases – diseases which can incubate and spread with alarming speed.

Marginalised communities without access to vaccination are home to most of the world's "zero-dose" children, two thirds of whom live below the poverty line. These communities are also less likely to have access to other basic health services and information. Gavi's focus is on tackling low coverage and inequity in immunisation by leveraging the power of vaccines and targeted health system strengthening investments, to help put in place the platform needed to deliver equity-driven primary health care services at both national and subnational levels. In particular, delivering immunisation and nutrition programmes together can help to maximise results and minimise costs of these critical health services, enabling more people to be reached, especially in vulnerable communities.

The same communities who are unable to access regular prevention are also the ones most likely to be at the epicentre of deadly epidemics and pandemics of infectious disease. Such outbreaks not only risk jeopardising the achievements of national routine immunisation programmes but also, given the enormous increase in human mobility, threaten global health security. Gavi will help protect the world against disease outbreaks by supporting both routine immunisation and frontline defence with emergency stockpiles and contribute to a world free of polio.

¹ Advance Market Commitment

Immunised communities will be healthier and better educated, household economics will be bolstered and the next generation, both boys and girls, will grow up to become more productive members of society. While girls and boys have equal access to vaccination globally, gender barriers faced by their mothers or caregivers affects their chances of being immunised. A gender-focused approach to vaccination programmes will further ensure that men and women become active agents in their children's immunisation.

In the period 2021–2025 the Alliance is **addressing inequities and providing the most comprehensive package of life-saving vaccines to Gavi-supported countries**. Gavi will continue to increase the reach of pentavalent, pneumococcal and rotavirus vaccines, preventing the deaths of millions of children from the most widespread childhood killers. The continued scale-up and introduction of vaccines, particularly pneumococcal, rotavirus, typhoid and meningococcal vaccines, will contribute to combatting antimicrobial resistance (AMR) by preventing illness and the use of antibiotics. The Alliance will work with countries to prioritise Gavi support, continuing the vaccine introduction agenda while assisting to identify vaccines that are most appropriate for their context.

Routine immunisation programmes were hit hard by the pandemic, with Gavi-supported countries seeing a 4% drop in vaccine coverage in 2020 – the first drop since Gavi was established in 2000 – and a 3.1 million increase in the number of zero-dose children, who receive no doses of the basic diphtheria, tetanus and pertussis vaccine (DTP). Since 2000, DTP3 coverage in lower-income countries had increased from 59% to 82% in 2019, close to the global average of 85%, with the Vaccine Alliance playing a key role in this progress. With coverage slipping to 79% in 2020, Gavi also has an important role to play in helping countries to recover from the pandemic.

Routine immunisation programmes require a trusted and strong primary health care system, comprising health workers to administer the vaccines regularly and safely in every community; robust supply chains to ensure vaccines are available where they are needed, including adequate cold chains to protect vaccines from damage from exposure to heat or freezing; and the ability to engage parents so that they understand the need for, and actively seek, immunisation. Every year, the number of births in Gavi-supported countries increases, which means that immunisation programmes need to immunise more children just to maintain the same level of coverage. The Alliance's ambition is to increase the level of coverage and reach every child with immunisation. Gavi's health system strengthening funding is targeted and tailored to subnational contexts, to tackle the urgent needs of communities yet to be reached. A focus on gender is central to address the strong connection between gender-related barriers and immunisation inequities. Renewed emphasis on other key barriers to equity, such as quality of services and unlocking demand for immunisation, will put missed communities first.

Gavi aims to focus its support on the world's poorest countries and bases eligibility on national income. Countries become eligible for our support if their average Gross National Income (GNI) per capita has been less than or equal to US\$ 1,630 over the past three years (according to World Bank data published in July each year). Once a country crosses the eligibility threshold, it enters the accelerated transition phase and starts to phase out of our financial support. Gavi also sets specific criteria for each type of support, as outlined in the application guidelines. All country applications are reviewed by a group of independent experts in routine immunisation, health system strengthening, epidemiology and disease control, cold chain and logistics, financial and budget analysis, and gender and equity. In 2020, 57 countries are eligible to apply for new vaccine support from Gavi.

Global climate change not only worsens annual weather patterns and their effects, but can also affect the epidemiology of these infections, spreading them beyond the regions where they were historically endemic and potentially further increasing the risk of epidemics. Gavi is helping lower-income countries introduce several vaccines against diseases that are worsened by these shifting weather patterns, including measles, meningitis, yellow fever, rotavirus and cholera. Gavi also works to bring improved or new vaccines to the market so that countries can continue to meet these challenges.

Gavi promotes cold chain equipment improvements within countries' immunisation supply chains, because effective and efficient cold chain equipment means vaccines can not only reach more people, but it also reduces waste in the supply chain. Gavi's Cold Chain Equipment Optimisation Platform 5 supports countries to upgrade to energy-efficient cold chain equipment, such as solar refrigeration, which reduces reliance on greenhouse-gas-emitting fuels such as kerosene. With Gavi support, countries are introducing an increasing number of vaccines. New technologies, like combination vaccines (such as pentavalent vaccine), can minimise waste by reducing the number of injections needed. Paired with a switch to multi-dose vials, this can help reduce the total number of

syringes and vials transported through the supply chain. Gavi also encourages countries to have immunisation waste management plans compliant with WHO standards.

Introduction and scaling up coverage of high-impact vaccines in eligible countries will continue to be at the heart of the Gavi strategy, as a clear comparative advantage for the Alliance. With Gavi support, all Gavi-eligible countries have now introduced pentavalent vaccine, 82% of Gavi-eligible countries have introduced Pneumococcal (PCV) vaccine and 64% have introduced Rotavirus vaccine 4 . While significant progress has been made, a number of countries are still missing some key vaccines (e.g. only 16% have introduced the Human Papilloma Virus (HPV) vaccine). The Alliance needs to continue its introduction agenda particularly in the most fragile countries where vaccines can have the highest impact on child mortality.

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

Rather than duplicate the services of the many players in the field of health and vaccines, **Gavi relies on country-based systems and works with partners with widespread field presence to deliver its programmes**. This keeps burdensome transaction costs down for implementing country governments.

- Gavi is not present on the ground in developing countries. Instead health ministries take the lead working closely with WHO regional and country offices, who provide expert recommendations on vaccine use and appraisal of new vaccines;
- Gavi provides funding for vaccine procurement, but UNICEF's supply division makes the purchases;
- The World Bank gives strategic advice on capital market dynamics and plays a key role in innovative financing;
- Gavi-funded vaccines reach villages in the poorest, most remote parts of the world thanks to in-country health systems and civil society organisations that deliver the life-saving vials to health centres.

The Gavi Board, representing the primary stakeholders in immunisation, deliberates and decides on the strategies, policies and approaches required to deliver on the Gavi mandate. The Gavi Board is comprised of UNICEF, WHO, the World Bank and the Bill & Melinda Gates Foundation, constituency representatives and independent Board Members. Constituencies comprise the governments of implementing countries; vaccine industry developing countries and industrialised countries, civil society organisations, and the governments of donor countries. The European Commission holds a joint constituency currently with Germany, France, Ireland and Luxembourg.

The Alliance's model is driven by implementing countries which co-finance vaccines, investing domestic resources to ensure their communities are immunised. Gavi's transition model has been supporting greater country ownership of national immunisation programmes. Gavi's model is a unique approach to sustainability and domestic resource mobilisation for vaccines, and has been highly successful in driving country financing towards immunisation. Partnership with civil society organisations (CSOs) helps to reinforce political commitment to immunisation at the national level. Through their connections to communities, many CSOs are uniquely placed to help identify and overcome barriers to immunisation, mobilise demand for vaccines and assist with vaccine confidence, deliver services to the most vulnerable and bring the voices of those communities to shape national decision-making and accountability.

Driven by countries, Gavi's collaborative model will continue to expand moving forward. The Vaccine Alliance's inclusive approach will further engage communities and civil society, and promote a growing ecosystem of public, private and social sector partners, bringing expertise and capacity to address countries' self-identified needs. Gavi in partnership with the Scaling Up Nutrition (SUN) Movement has launched an innovative two-pronged healthcare approach by integrating immunisation and nutrition services and thereby ensuring that more people can be reached, especially the vulnerable, women, and children.

3 DESCRIPTION OF THE ACTION

3.1 Objectives and Expected Outputs

The **Overall Objective (Impact)** of this action is to save lives and protect people's health by increasing equitable and sustainable use of vaccines.

The **Specific Objective (Outcome)** 1 of this action is the introduction of life-saving vaccines and scaling up of vaccine coverage.

The **Output** to be delivered by this action contributing to the corresponding Specific Objective (Outcome) is:

1.1 Children vaccinated with support received

3.2 Indicative Activities

Activities relating to Outcome 1:

- Strengthen countries' prioritisation of vaccines appropriate to their context.
- Support countries to introduce and scale up coverage of vaccines for prevention of endemic and epidemic diseases.
- Enhance outbreak response through availability and strategic allocation of vaccine stockpiles

Over the 5.0 period, Gavi will deliver over 3.2 billion doses of life-saving vaccines to 55 eligible countries. It will fund vaccine stockpiles for emergency use to stop dangerous outbreaks and insure the world against polio re-emergence through implementing routine inactivated polio vaccine (IPV) programmes across Gavi countries, in collaboration with the Global Polio Eradication Initiative (GPEI).

3.3 Mainstreaming

Environmental Protection & Climate Change

Outcomes of the SEA screening: Not applicable

Outcomes of the EIA (Environmental Impact Assessment) screening: Not applicable

Outcome of the CRA (Climate Risk Assessment) screening: Not applicable

Gavi's vaccine programmes help communities, particularly the most marginalised, build resilience and mitigate the risk of disease outbreaks tied to climate change by preventing infection in the first place. Immunisation helps protect communities from vector-borne, water-borne and diarrhoeal diseases sensitive to climate and environmental changes, such as yellow fever, rotavirus, meningitis A, oral cholera, Japanese encephalitis, Ebola and typhoid. Gavi supports countries to upgrade to efficient, climate-friendly cold chain equipment since up to 90% of medical facilities lacked modern equipment in 2019 to reduce their healthcare related footprint. As part of its pledge at the 2019 Climate Action Summit to scale up investments in proven interventions for climate-resilient health systems, Gavi contributes to greater energy efficiency through the cold chain equipment optimisation platform (CCEOP), offering countries support for solar direct drive (SDD) and ice-lined refrigeration (ILR) – which are more reliable and more energy-efficient than traditional refrigerator devices.

Gender equality and empowerment of women and girls

As per the OECD Gender DAC codes identified in section 1.1, this action is labelled as G1. Gavi will continue to contribute to SDG5 through its gender-transformative approach to health. Over the course of 5.0, Gavi will increasingly seek to understand the causal relationship between gender and poverty, as well as address a misunderstanding of the relationships between genders, through equity assessments and the collection of sex-disaggregated data to ensure gender is not a barrier to immunisation. Investing with countries through a gender lens that empowers those who are marginalised to voice their concerns and influence decisions will help to bring preventive health services to those who can least afford the consequences of illness, thereby fostering equitable

prosperity. A gender-focused approach to vaccination programmes will further ensure that men and women become active agents in their children's immunisation.

Immunisation is a gender-equal intervention. Globally, girls and boys are immunised at similar rates. However, there are variations at subnational levels and in some countries because a range of different barriers inhibit women's ability to access healthcare for their children. Gavi supports countries' efforts to identify and address gender-related barriers to immunisation services, e.g. through training female health workers, as empowering women is critical to improving child vaccination coverage.

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

The Gavi gender policy recognises that overcoming gender-related barriers and ensuring equal access between genders is a key factor to expanding immunisation coverage and reinforcing health systems. In June 2020, a revised policy was approved by the Gavi Board, with three new goals:

1. Focusing primarily on identifying and addressing underlying gender-related barriers faced specifically by caregivers, adolescents and health workers.
 2. In the specific pockets where they exist, overcoming differences in immunisation coverage between girls and boys.
 3. Encouraging and advocating for women's and girls' full and equal participation in decision-making related to health programmes and wellbeing.
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Human Rights

Access to life-saving immunisation is a fundamental human right. Gender equality is a fundamental human right and a powerful driver for better health outcomes globally. By promoting gender-responsive and transformative programming, Gavi will not only reach zero-dose and underimmunised children, individuals and communities but also contribute to Sustainable Development Goal 5 of gender equality and the empowerment of women and girls.

Disability

As per OECD Disability DAC codes identified in section 1.1, this action is labelled as D1. This implies that a significant objective of Gavi's mission is to prevent disability through routine immunisation against diseases with the potential to disable such as polio. Gavi will continue efforts to insure the world against polio re-emergence through implementing routine inactivated polio vaccine (IPV) programmes across Gavi countries, in collaboration with the Global Polio Eradication Initiative. Furthermore, through its targeted investments to support delivery of healthcare, Gavi is contributing to more integrated health systems overall, meaning countries are better equipped to provide healthcare beyond routine immunisation. With immunisation comes supply chain, trained staff, data monitoring, disease surveillance, community outreach, health records, emergency coordination and social mobilisation, all of which serve as a platform for health integration with other public healthcare interventions.

Democracy

Beyond being a major contributor to the SDG3 aspiration of healthy lives and promotion of well-being for all, immunisation is an essential ingredient for most other SDGs². Immunised communities will be healthier and better educated, household economics will be bolstered and the next generation, both boys and girls, will grow up to become more productive members of society.

Conflict sensitivity, peace and resilience

Effective, safe, and people-centred health systems are the backbone of social institutions in every country, and immunisation is often the first point of contact between these systems and the population. Through Gavi support, countries' efforts to improve equitable access to vaccines contributes to building public trust, stronger social cohesion, peaceful and inclusive societies.

Disaster Risk Reduction

The impact of climate change cuts across health and well-being, livelihood, and security of people, particularly for the poorest and most vulnerable communities, such as people on the move. Immunisation is critical to building people's and systems' resilience to and reducing the risk of outbreaks due to climate-sensitive diseases, such as yellow fever, cholera and Ebola, particularly in urban, fragile and post disaster settings.

Other considerations if relevant

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

3.4 Risks and Lessons Learnt

Category	Risks	Likelihood (High/ Medium/ Low)	Impact (High/ Medium/ Low)	Mitigating measures
External environment	Availability of vaccine is not sustained and price is too volatile	M	H	Gavi will continue to work on balancing all the elements necessary to ensure sustainable and healthy market dynamics for vaccines and immunisation-related products, focusing on reliable, consistent and affordable supply as an overarching objective.
People and the organisation	Lack of ownership and set-up of parallel structures in countries	L	M	Joint donor coordination Alignment to national systems advocated by EU at the Gavi Board
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.
People and the organisation	Significant COVID-19 delivery issues and impact	H	H	COVAX Pillar partners are actively monitoring key delivery risks through weekly 'implementation monitoring

	on routine immunisation			reviews' and defining targeted interventions for high risk countries (e.g. accelerating access to funding for delivery when there are gaps, adjusting future shipments and allocation based on absorption, informing the next allocation round with product preference, considering redeployment of doses within or outside the country, and providing specific technical assistance based on country implementation gaps). Sufficient COVID-19 delivery funding will also help in mitigating the potential impact on routine immunisation and at the same time be used to exploit synergies where possible.
External environment	Insufficient demand: Significant drop or insufficient increase in vaccine demand due to hesitancy and lack of prioritisation.	H	H	The Alliance's demand generation framework includes building vaccine confidence and trust as a central component. In the context of COVID-19, the Alliance continues to intensify its efforts to actively generate demand for vaccines.
People and the organisation	Sustainable transition: Some countries may fail to sustain progress of their immunisation programmes after transition.	H	H	To manage this risk, Gavi's approach to sustainability continues to emphasise the importance of engaging early with countries to build and strengthen the financing, systems, and capacities needed to deliver on sustainable coverage and equity. Countries nearing transition undergoing Full Portfolio Planning are developing their transition plans as an integral part of this process. Countries also share their experiences and learn from each other through dedicated platforms, such as the Learning Network for Countries in Transition (LNCT), a peer-exchange network for transitioning and transitioned countries.
People and the organisation	Partner capacity: Sum of comparative advantages of Alliance partners is inadequate to effectively deliver required technical support to countries.	M	H	To manage this risk, the Partners' Engagement Framework (PEF) model leverages the comparative advantage of core partners (WHO, UNICEF, World Bank and CDC) as well as over 50 expanded partners (including 14 local partners), bringing new areas of comparative advantage. It has focussed on delivering more partner capacity directly to countries (with technical support now provided at subnational level in 25 countries), and further enhanced the

				effectiveness, efficiency and transparency of collaboration with core partners. Technical Assistance (TA) guidance includes a specific section on “Transfer of skills” to ensure sustainability of TA.
Lessons Learnt: Lessons learned in the previous period will be applied to build on success. While most countries transition from Gavi support with high coverage and strong financing performance, they still have specific, clearly defined challenges, many of which are linked to their institutional development. These include gaps in programme management and regulatory capacity, inefficient vaccine procurement practices and some missed vaccine introductions. To address these gaps and minimise any risks of backsliding, the Gavi Board has recognised the importance of putting in place an engagement approach with countries post-transition, focused on political advocacy, targeted technical assistance, innovation, market shaping and catalytic short-term financial support to jump-start new vaccine introductions. This will ultimately catalyse the more efficient and effective use of countries’ own domestic resources allocated to immunisation.				

3.5 The Intervention Logic

The underlying intervention logic for this action is that it contributes directly to the overall objective of the GC People pillar to strengthen the EU as a leading global actor in supporting the global agenda for inclusive and equal societies and human development for all, with a specific focus on women and girls, children, young people, and other populations living in vulnerable situations. This action contributes to a partnership designed to support Gavi’s mission to save lives and protect people’s health by increasing equitable and sustainable use of vaccines. Total forecast Expenditure is EUR 9,8 billion for Gavi 5.0 in 2021-2025 to support programmes in more than 57 low income countries eligible for Gavi support.

This action also contributes directly to the GC specific Health objective to strengthen EU leadership in global health and support the achievement of the SDG 3.

This action will contribute towards the Gavi 5.0 programme for 2021-2025, that is Gavi’s core business, specifically the pillar to introduce and scale up vaccines. This action does not provide specific funding for the COVAX facility.

Gavi’s vision of ‘leaving no one behind with immunisation’ recognises the link with the SDG ambition and the critical contribution of immunisation to it. The vision highlights the opportunity to reach all children with immunisation by the end of the SDG era, as one of the few health interventions where universalism seems realistically achievable within the SDG timeframe. In delivering on its vision, Gavi’s mission will be: “To save lives and protect people’s health by increasing coverage and equitable use of vaccines”. The mission puts ‘equity’ at the heart of the strategy. ‘Coverage’ includes attention to individual antigens but also the concept of the fully immunised child. The mission also recognises the fact that vaccines protect people at all stages of life, by preventing both the primary causes of mortality in children (including diarrhoea and pneumonia) and preventing cancers later in life triggered by vaccine-preventable infections (such as cervical cancer from HPV and liver cancer from hepatitis B).

Gavi has four strategic goals in this period:

- Strategic Goal 1: Introduce and Scale up Vaccines
- Strategic Goal 2: Strengthen Health Systems to Increase Equity in Immunisation
- Strategic Goal 3: Improve Sustainability of Immunisation Programmes
- Strategic Goal 4: Ensure Healthy Markets for Vaccines and related Products

Gavi 5.0 is grounded in operating principles which contribute to key intervention areas as part of the theory of change, these principles are outlined in the 2021-2025 strategic framework overleaf and include: Missed communities as the first priority; gender focused; country-led, sustainable; community owned, differentiated; integrated; adaptive , resilient; innovative; collaborative, accountable. The framework also includes four “strategic enablers” that will

contribute to delivering on the new strategy. These are critical elements that the Alliance, including countries, need to put in place to successfully achieve the four strategic goals. They are:

- secure long-term predictable funding for Gavi programmes
- ensure global political commitment for immunisation, prevention and primary health care
- use evidence, evaluations and improved data for policies, programmes and accountability
- leverage the private sector, including through innovative finance mechanisms and partnerships

Details on these strategic goals are provided in the framework overleaf and further elaborated on in the theory of change. This action will focus on Strategic Goal 1: Introduce and Scale up Vaccines, specifically infant immunisation and introducing and scaling up vaccine coverage. Introduction and scaling up coverage of high-impact vaccines in eligible countries will continue to be at the heart of the Gavi strategy, as a clear comparative advantage for the Alliance. Gavi will support countries to strengthen vaccine prioritisation decisions, building increased capacity for evidence-based decision making which aims to lead to expanded breadth of protection through routine immunisation and vaccine-preventable disease is prevented and mitigated. The specific indicators in this action measures the increase in vaccine coverage, breadth of protection, percentage change in number of zero-dose children and future deaths averted.

In this strategic period there is an increased focus on equity, which is the key organising principle of Gavi's support. This entails ensuring that services are extended as a priority to communities that are currently missed including refugees, displaced and other vulnerable populations. To deliver on this principle, the Alliance is applying a strong gender lens to address immunisation barriers, recognising the strong connection between gender related barriers and immunisation inequities and therefore the central role that gender should play to reach under-immunised communities. Similarly, the strategy takes a renewed emphasis on increasing community ownership, trust, and demand for immunisation services, and improving service delivery for under-served populations.

By supporting global immunisations efforts in the poorest countries through Gavi, the Commission will continue to participate in its governance structures and steer the strategy, priorities and implementation of this initiative in partnership with other major funders, and demonstrate the leadership and commitment to address global health challenges in practical ways.

The complementarity with national programmes actions will be further strengthened with a refinement of on-going approaches to secure domestic public resources for immunisation and more broadly for primary health care, recognising that immunisation services reach children most sustainably when embedded into strong Primary Health Care. GAVI will also maintain the approach of increased country ownership through co-financing of vaccines.

At country level, an annual joint appraisal is carried out, consisting of an in-country multi-stakeholder review of the implementation progress and performance of GAVI support to the country, and of its contribution to improved immunisation outcomes.

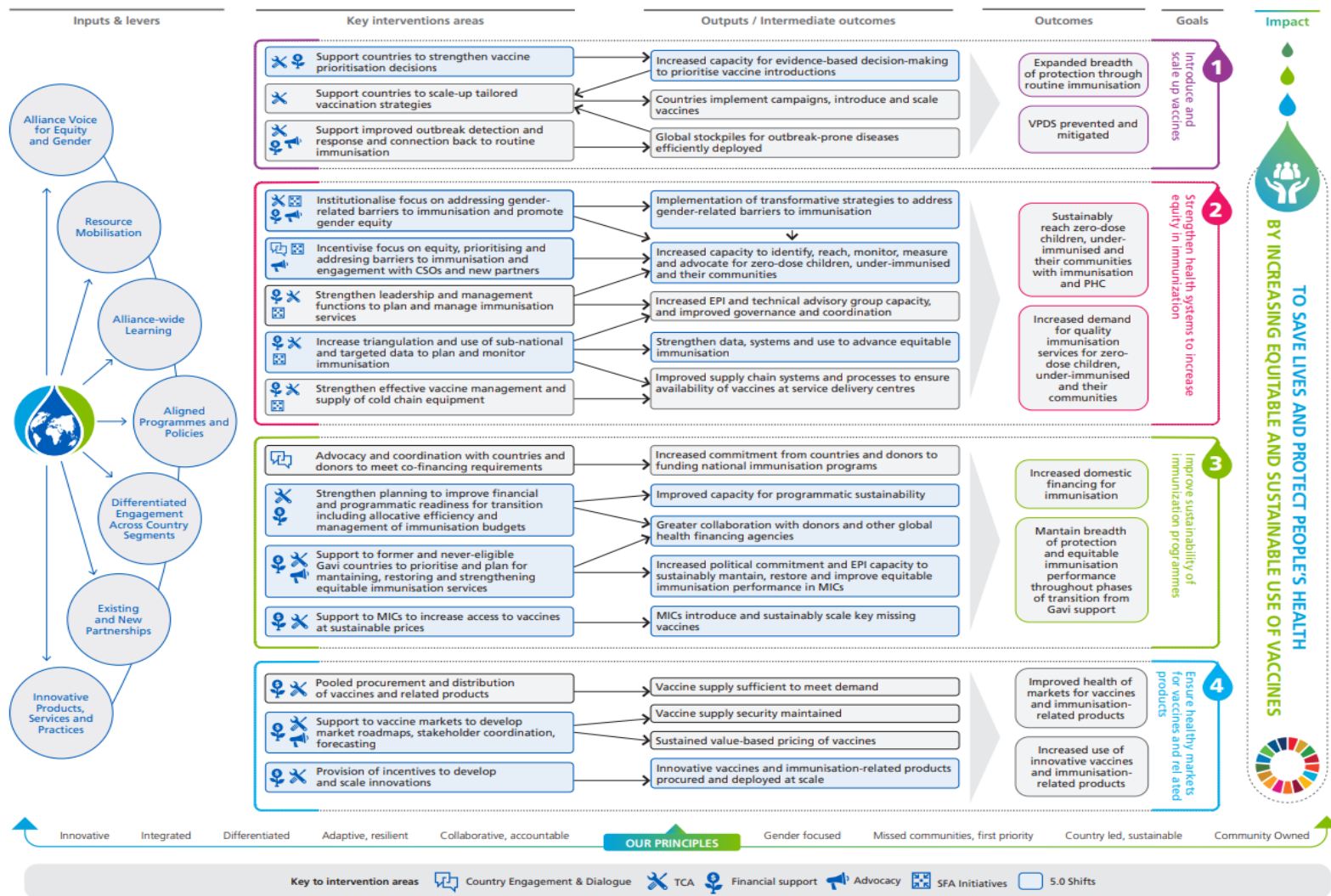
In order to achieve the longer term outcome, the EU, through its participation in its governance mechanisms and through a Team Europe approach, will ensure that GAVI accelerates progress on integrating immunisation programmes into primary health care, ensures wider participation in the Inter-Agency Coordinating Committee (ICC) by health systems and UHC partners including Ministries of Finance, and increases focus on domestic health financing and sustainability.

In addition to increased and better coordinated investments to strengthen health and immunisation systems with the other global health initiatives and agencies, the EU also expects a more practical framework for these investments, including agreed joint monitoring, tracking and results measurements.

Gavi, the Vaccine Alliance: 2021–2025 Strategy

Vision		Leaving no one behind with immunisation		SUSTAINABLE DEVELOPMENT GOALS	
Mission 2025	To save lives and protect people's health by increasing equitable and sustainable use of vaccines	Mission Indicators	<ul style="list-style-type: none">Under-five child mortality reduction -10%Future deaths averted 7–8mFuture DALYs averted 320–380m	<ul style="list-style-type: none">Reduction in zero-dose children (equity indicator) -25%Unique children immunised 300mEconomic benefits unlocked US\$80–100bn	
Principles	<ul style="list-style-type: none">Missed communities, first priority: Prioritise children missing out on vaccination, including among migrants, displaced and other vulnerable populationsGender-focussed: Identify and address gender-related barriers to promote immunisation equityCountry-led, sustainable: Bolster country leadership to sustainably deliver and finance immunisationCommunity-owned: Ensure community trust and confidence in vaccines by engaging communities in planning, implementation and oversight of immunisationDifferentiated: Target and tailor support to national and subnational needs, including fragile contexts <ul style="list-style-type: none">Integrated: Strengthen immunisation as a foundation for integrated primary health care to reach unserved communities in support of universal health coverageAdaptive, resilient: Help countries leverage immunisation to address the challenges of climate change, Global Health Security, antimicrobial resistance and other major global issuesInnovative: Identify and leverage innovative products, practices and services to reach everyone with immunisationCollaborative, accountable: Collaborate across stakeholders to achieve the SDGs in a transparent, coordinated and accountable manner				
Goals	<div>1 INTRODUCE AND SCALE UP VACCINES</div> <div>2 STRENGTHEN HEALTH SYSTEMS TO INCREASE EQUITY IN IMMUNISATION</div> <div>3 IMPROVE SUSTAINABILITY OF IMMUNISATION PROGRAMMES</div> <div>4 ENSURE HEALTHY MARKETS FOR VACCINES AND RELATED PRODUCTS</div>				
Objectives	<div><div>A Strengthen countries' prioritisation of vaccines appropriate to their context</div><div>B Support countries to introduce and scale up coverage of vaccines for prevention of endemic and epidemic diseases</div><div>C Enhance outbreak response through availability and strategic allocation of vaccine stockpiles</div></div> <div><div>A Help countries extend immunisation services to regularly reach under-immunised and zero-dose children to build a stronger primary health care platform</div><div>B Support countries to ensure immunisation services are well-managed, sustainable, harness innovation and meet the needs of all caregiver</div><div>C Work with countries and communities to build resilient demand, and to identify and address gender-related barriers to immunisation</div></div> <div><div>A Strengthen national and subnational political and social commitment to immunisation</div><div>B Promote domestic public resources for immunisation and primary health care to improve allocative efficiency</div><div>C Prepare and engage self-financing countries to maintain or increase performance</div></div> <div><div>A Ensure sustainable, healthy market dynamics for vaccines and immunisation-related products at affordable prices</div><div>B Incentivise innovation for the development of suitable vaccines</div><div>C Scale up innovative immunisation-related products</div></div>				
Enablers	<ul style="list-style-type: none">Secure long-term predictable funding for Gavi programmesEnsure global political commitment for immunisation, prevention and primary health careUse evidence, evaluations and improved data for policies, programmes and accountabilityLeverage the private sector, including through innovative finance mechanisms and partnerships				

Theory of Change



² The theory of change is due to be updated in mid-2022 to account for and reflect the evolution of the changed context and priorities for Gavi's programming. The COVID19 pandemic prompted changes in thinking, priorities and plans for how (and when) Gavi's programming would be operationalized. The Gavi Board initially recalibrated Gavi 5.0 priorities in in September 2020. In doing so, they determined new priorities, reaffirmed the importance of retain specific aspects of Gavi 5.0's original priorities, and "rephased" (deprioritized/postponed) other aspects of Gavi's plans for the strategy period. These discussions remain ongoing as Gavi continues to balance the needs to respond to the pandemic and remain focused on its core mission.

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 (e): Main expected results (maximum 10)	Indicators (e): (at least one indicator per expected result)	Baselines ^{3,4} (values and years)	Targets (values and years)	Sources of data	Assumptions
Impact	To save lives and protect people's health by increasing equitable and sustainable use of vaccines	1. Percentage change in number of zero-dose children 2. Unique Children Immunized with EU support ⁵ 3. Future deaths averted	1. 9.7m 2. n/a 3. n/a	1. -25% 2. 300m 3. 7-8m	1,2. WHO/UNICEF Estimates of Immunisation Coverage; United Nations Population Division, World Population Prospects 3. Vaccine Impact Modelling Consortium	<i>Not applicable</i>
Outcome 1	1. Life-saving vaccines introduced and scaled up	1.1 Breadth of protection ⁶ 1.2 Coverage of Pneumococcal conjugate vaccine (3 rd dose) 1.3 Coverage of Measles containing vaccine (1 st dose) 1.4 Coverage of Rotavirus vaccine 1.5 Coverage of Pentavalent vaccine 1.6 Coverage of Innoculated Polio Vaccine (IPV)	1.1 56% 1.2 53% 1.3 81% 1.4 50% 1.5 82% 1.6 77%	1.1. +16pp 1.2. +23pp 1.3. +4pp 1.4. TBD ⁷ 1.5. +4pp 1.6. TBD ⁸	WHO/UNICEF Estimates of Immunisation Coverage; United Nations Population Division, World Population Prospects	Continued stable supply of vaccines from manufacturers Country applications approved by Gavi
Output 1 relating to Outcome 1	1.1 Children vaccinated with Gavi-supported vaccines	1.1.1 Number of children vaccinated with Pneumococcal conjugate vaccine (3 rd dose) 1.1.2 Number of children vaccinated with Measles containing vaccine (1 st dose) 1.1.3 Number of children vaccinated with Rotavirus vaccine 1.1.4 Number of children vaccinated with Pentavalent vaccine 1.1.5 Number of children vaccinated with Innoculated Polio Vaccine	1.1.1 38.8m 1.1.2 58.4m 1.1.3 36.4m 1.1.4 59.0m 1.1.5 55.9m	1.1.1 58m 1.1.2 64m 1.1.3 TBD ⁹ 1.1.4 64m 1.1.5 TBD ¹⁰	WHO/UNICEF Estimates of Immunisation Coverage; United Nations Population Division, World Population Prospects	

³ Baselines and targets for the impact and outcome indicators align with those included in the Measurement Framework for the Gavi 2021-2025 strategy. These were approved by the Gavi board. Baselines and targets for the output indicators are based on Gavi's internal forecasting data. These are internal documents and are not formally reviewed and approved by the Gavi Board.

⁴ Values for baselines and targets are subject to revision annually based on the historical amendments to the immunisation coverage estimates recommended by the WHO and UNICEF.

⁵ This indicator replaces the indicator 'Number of 1-year olds fully immunized with EU funding' originally proposed by the EC, given that:

Fully Immunised Child definition: Percentage of children in Gavi-supported countries that receive by their first birthday the last recommended dose of each of the 11 vaccines/antigens currently recommended by WHO for all countries' infant immunization schedules. The vaccines/antigens included are BCG, DTP3, Polio3, HepB3, Hib3, PCV3, Rota, MCV1, Rubella. Not all of these vaccines are within Gavi support and not all of the vaccines would be EC funded, therefore, it would not be an appropriate indicator for this action.

⁶ Breadth of Protection definition: Average vaccination coverage across all Gavi-supported vaccines in Gavi-supported countries. The vaccines/antigens included are pentavalent, pneumococcal, rotavirus, measles-containing vaccine second dose, rubella, inactivated polio vaccine (IPV), human papilloma virus (HPV), yellow fever, Japanese encephalitis (JE), and meningitis type A.(Men A). Breadth of Protection counts all the children vaccinated with the last recommended dose of Gavi-supported routine vaccinations in Gavi-supported countries whereas the FIC only counts the children that received all 11 antigens/vaccines.

⁷ Target to be determined May/June 2022

⁸ Target to be determined May/June 2022

⁹ Target to be determined May/June 2022

¹⁰ Target to be determined May/June 2022

4 IMPLEMENTATION ARRANGEMENTS

4.1 Financing Agreement

In order to implement this action, it is not envisaged 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 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 measures¹¹.

4.3.1 Direct Management (Grants)

Grants: (direct management)

(a) Purpose of the grant(s)

The Overall Objective of this action is to save lives and protect people's health by increasing equitable and sustainable use of vaccines, by introducing and scaling up vaccines.

The Specific Objective (Outcome) 1 of this action is the introduction of life-saving vaccines and scaling up of vaccine coverage.

(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, in accordance with article 195(c) of Regulation (EU) 2018/1046, because the beneficiary is in a de facto monopoly situation:

Gavi is a public-private global health partnership – a global Vaccine Alliance, bringing together public and private sectors with the shared goal of saving lives and protecting people's health by increasing equitable and sustainable use of vaccines. Gavi has a solid record of accomplishment in the immunisation field, acting at the same time as fundraiser of funding for procurement of new vaccines, shaping the vaccine market, and working with countries to strengthen their immunisation systems. Gavi spends on average US\$ 1 billion per year on delivering vaccine programmes to the 57 poorest countries. Gavi is the only entity providing such pooled procurement mechanism to purchase vaccines for low and middle income countries on a global scale.

(c) Exception to the non-retroactivity of costs

The Commission authorises that the costs incurred may be recognised as eligible as of 1 January 2022 a date prior to the adoption of this Decision because the strategic period which this action aims to support began in 2021 and there are vaccine programmes which are already in need of this funding as of this year. This retroactive funding will also ensure that the EU funding can be applied to the Commission's prioritised programmes in support of this action.

¹¹ www.sanctionsmap.eu. Please note that the sanctions map is an IT tool for identifying the sanctions regimes. The source of the sanctions stems from legal acts published in the Official Journal (OJ). In case of discrepancy between the published legal acts and the updates on the website it is the OJ version that prevails.

4.4. Scope of geographical eligibility for procurement and grants

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

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

4.5. Indicative Budget

Indicative Budget components	EU contribution (amount in EUR)	Third-party contribution, in EUR
Grants – total envelope under section 4.3.1	300 million	
Evaluation – cf. section 5.2 Audit – cf. section 5.3	May be covered by another Decision	N.A.
Totals	300 million	9,8 billion

4.6. Organisational Set-up and Responsibilities

The European Commission is a member of a Gavi Board constituency and currently the Alternate Board Member for that constituency and is due to hold the Board seat next year. As such, the European Commission had a direct influence on the establishment of the Gavi 5.0 strategy and the vaccine programme which this action will support. 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 Board regularly receives financial updates with details of expenditures for Gavi programmes by year. In addition, Gavi maintains regular contact with the Commission on the progress of the action at the working level and provides formal narrative reports on the outcomes.

Gavi relies on country-based systems and works with partners with widespread field presence to deliver its programmes. Driven by countries, Gavi's collaborative model has an inclusive approach which engages communities and civil society, promoting a growing ecosystem of public, private and social sector partners, bringing expertise and capacity to address countries' self-identified needs.

Gavi is committed to creating a work environment that is safe and professional, where people work together in an atmosphere of mutual trust, where diversity and inclusion are valued and where everyone is treated with courtesy and respect.

As part of its prerogative of budget implementation and to safeguard the financial interests of the Union, the Commission may participate in the Gavi 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 (for project modality) and the partner's strategy, policy or reform action plan list (for budget support).

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

Roles and responsibilities for data collection, analysis and monitoring:

The monitoring and evaluation system for Gavi 5.0 identifies the tools and processes to enable learning and improve performance management for delivering on the Gavi 5.0 strategy goals and objectives.

The use of theory of change allows Gavi to clearly articulate the 5.0 strategy in a way that enhances our ability to monitor and evaluate it. Theory of change is an approach that defines the causal pathways by which inputs and processes (e.g. Gavi strategy and support) produce the intended outputs (e.g. vaccine introduction and scale-up) and lead to outcomes (e.g. children immunised) and impact (e.g. deaths averted).

For monitoring, Gavi uses a theory of change approach with indicators that are linked to the 5.0 strategy objectives and, due to their location along causal pathways, will indicate not only whether the Alliance is on track to meet its objectives, but also where it is off-track allowing for more real-time course correction as part of performance management. For evaluations, understanding our theory of change will help identify the key learning questions of strategic importance to the Gavi Board and allow for development of the evaluation workplan for Gavi 5.0 at the outset of the strategy period which will be approved and overseen by the Evaluation Advisory Committee with input from the Board.

Strategy implementation includes tracking input, process and output indicators measuring activities carried out by the Gavi Secretariat, Alliance partners and countries supporting implementation of the Gavi 5.0 strategy. Strategy performance measurement measures progress towards achievement of the strategy goals and objectives (i.e. the outputs, outcomes and impact), with shared accountability across the Alliance and reporting to the Gavi Board.

Alliance ownership of strategy goals and objectives, indicators and targets:

- To avoid lack of alignment between indicators for the measurement framework and Gavi's strategy and investments, business owners across the Alliance played an active role in developing indicators.
- Coordination with Immunization Agenda 2030 M&E framework development and country-level and regional/global M&E frameworks to the extent possible will simplify processes, utilise existing data systems, reduce data collection and monitoring burden and help ensure broader ownership of the Gavi 5.0 strategy performance indicators.
- Target setting is data driven, based on the assumptions underlying our theory of change and the investments planned for achieving Gavi 5.0 strategic objectives.

The indicators for this action are part of Gavi's strategic indicators and as such monitored through our monitoring and evaluation system as described above. WHO/UNICEF estimates of immunisation coverage and number of children immunised at the country level are used by Gavi to monitor progress and this data be reported to the European Commission to show progress on this action.

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 may be shared with the partners 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, apply the necessary adjustments.

Evaluation services may be contracted under a framework contract.

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

5.3 Audit and Verifications

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

6 STRATEGIC COMMUNICATION AND PUBLIC DIPLOMACY

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

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

However, in line with Article 46 and subject to Article 47 of the NDICI Regulation, all entities implementing EU-funded external actions shall take all reasonable measures to publicise the European Union support. This obligation will continue to apply equally, regardless of whether the actions concerned are implemented by the Commission, partner countries, service providers, grant beneficiaries or entrusted or delegated entities such as UN agencies, international financial institutions and agencies of EU member states.

Appendix - 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	Direct management – grant to Gavi, the Vaccines Alliance