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ANNEX II

to the Commission Implementing Decision on the financing of the multiannual action plan in favour of the Americas and the Caribbean for 2024 part V and 2025 part II

Action Document for PharmaNext: The Caribbean – EU Bridge for advancing Pharma and Life Sciences for all

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

<p>1. Title CRIS/OPSYS business reference Basic Act</p>	<p>PharmaNext: The Caribbean – EU Bridge for advancing Pharma and Life Sciences for all OPSYS number: ACT-62489 Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe)</p>
<p>2. Team Europe Initiative</p>	<p>No</p>
<p>3. Zone benefiting from the action</p>	<p>The action shall be carried out in the Caribbean region, Barbados and Guyana</p>
<p>4. Programming document</p>	<p>The Americas and the Caribbean Regional Multiannual Indicative Programme 2021-2027</p>
<p>5. Link with relevant MIP(s) objectives / expected results</p>	<p>Priority area 5: Social cohesion and addressing inequalities</p> <ul style="list-style-type: none"> - Specific Objective 3: Strengthening systems to protect people from risks and ensure equal access to education and other public goods and services including decent work (particularly for women and the most vulnerable). - R1: All people have increased access to quality basic services (health, water and sanitation, education and skills development, employment, access to justice), including at territorial level; <p>Caribbean window</p> <ul style="list-style-type: none"> - Caribbean-EU Partnership for governance, security and human development - Specific Objective 1: Caribbean societies are safer, more inclusive and resilient. <p>R2: Communities are more cohesive and better protected against health threats and external shocks, in particular women and youth</p> <p>Guyana window – MIP following MTR</p> <ol style="list-style-type: none"> 1. Guyana: Development and manufacturing of health products and strengthening of health care system

PRIORITY AREAS AND SECTOR INFORMATION				
6. Priority Area(s), sectors	121 medical research 122 basic health care			
7. Sustainable Development Goals (SDGs)	Main SDG (1 only): 3: Ensure healthy lives and promote well-being for all at all ages Other significant SDGs (up to 9) and where appropriate, targets: SDG 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all SDG 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation SDG10: Reduce inequality within and among countries SDG 17: Strengthen the means of implementation and revitalize the Global Partnership for Sustainable Development			
8 a) DAC code(s)	121 - Medical research – 60 122 – Basic Health Care – 40			
8 b) Main Delivery Channel	11 004			
9. Targets	<input type="checkbox"/> Migration <input type="checkbox"/> Climate <input checked="" type="checkbox"/> Social inclusion and Human Development <input type="checkbox"/> Gender <input type="checkbox"/> Biodiversity <input checked="" 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"/>
	Reproductive, maternal, new-born and child health	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Disaster Risk Reduction @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Inclusion of persons with Disabilities @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Nutrition @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	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 @	<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 type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	/
	Connectivity @	<input 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"/>	NO <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	/
	Migration @	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	Reduction of Inequalities @	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	Covid-19	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	BUDGET INFORMATION			
12. Amounts concerned	<p>Budget line: 14.020141</p> <p>Total estimated cost: EUR 8,900,000</p> <p>Total amount of EU budget contribution: EUR 8,900,000</p> <p>The contribution is for an amount of EUR 8,900,000 from the general budget of the European Union, EUR 5,000,000 from the general budget of the European Union for financial year 2024 and for an amount of EUR 3,900,000 from the general budget of the European Union for financial year 2025, 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.</p>			
MANAGEMENT AND IMPLEMENTATION				
13. Type of financing	<p>Direct management through:</p> <p>- Grants</p>			

1.2 Summary of the Action

The European Union – Latin American and the Caribbean (EU-LAC) partnership on health resilience and vaccine production initiative, signed by President von der Leyen and Spanish President Sanchez in June of 2022 aims to foster cooperation in research and development, technology transfer, regulatory strengthening, and private sector involvement. Through this the EU seeks to promote particular interest in: Regulatory harmonisation and particularly promotion of reliance on EU regulatory standards; Access to primary research and cooperation on applied research; creation of investment opportunity for EU private sector. These priorities align with the Community of Latin American and Caribbean States' (CELAC) "Plan for self-sufficiency in health matters in Latin America and the Caribbean " which underscores the strategic approach to strengthening capacities for producing and distributing vaccines and medicines, with support from the United Nations Economic Commission for Latin America and the Caribbean (ECLAC) and the Pan American Health Organization (PAHO).

The action “PharmaNext” builds on and operationalises the following initiatives included in the Global Gateway investment agenda for the Caribbean:

- 1- Regional – LAC – Health Resilience, which key priorities are to support the development of local medicines and vaccine manufacturing and health systems resilience, including regulatory frameworks.
- 2- Barbados: Health systems resilience and digital transformation of health facilities,
- 3- Guyana: Development and manufacturing of health products

The action also promotes higher standards for the pharma industries in the region and in Barbados and Guyana in particular, in line with the Global Gateway objectives, ensuring greater safety for its populations while helping local and regional pharma industry penetrate the European market.

The action implements the commitments made by Guyana and Barbados Heads of Government in 2022 (during the launch of the Pharma initiative in the presence of President Von Der Leyen and President Kagame from Rwanda) to effectively ensure an equitable access to medicines and vaccines for its populations through partnerships with the private sector and creating opportunities for investment in the region and Guyana in particular.

The action complements other existing EU interventions, notably EU’s support to PAHO work’s on ensuring Equitable access to health technologies and strengthening local manufacturing capacities in Latin America and the Caribbean (LAC). PharmaNext builds on prior and current EU support in the region to bring EU private sector investments that can build the resilience and self-sufficiency of national health systems, and in Barbados and Guyana in particular. In Barbados, the main central Hospital (Queen Elizabeth) has benefitted from loans from EIB and IDB, which the EU has strengthened with a grant (blending).

This action is sister to the “Support to the Implementation of the Economic Partnership Agreement (EPA) to Increase Trade and Investments with the EU (2024 – 2028) Phase 3 (ACT-62135)” which foresees a series of activities aiming at promoting EU investments and collaboration with the Pharmaceutical regional industry.

Most notably, the Caribbean Cooperation Facility will allow for the financing of (pre-)feasibility studies and EFSD+ will serve to provide financing for private sector investment, including the guarantee facility by the EIB and the Gates Foundation that include Barbados and the Caribbean as priority area.

REGIONAL INITIATIVE (GGIA)

GGIA impact: Increase health resilience in the Caribbean region.

Key priorities:

- 1- Support the development of local medicines,
- 2- Support development of vaccine manufacturing,
- 3- Strengthen regulatory frameworks.

The two regional grants will focus on:

Priority 1: support development of local medicines

Priority 2: Support development of vaccine manufacturing

- a. Development of professional and technical capacities for small local pharma manufacturers (e.g., training for the application of Good Manufacturing Practices) in partnership with EU Pharma companies and public institutions.
- b. For locally manufactured medical products, support for submission to the EUM4All procedures for authorization in collaboration with EU pharma firms and other stakeholders of the pharma value chain (including importing firms)
- c. Strengthen research for small local pharma manufacturers via collaboration with EU institutions and firms.
- d. Support technology transfer to ensure applied research (targeted) is brought to local markets: collaboration with technology transfer offices, universities and research-oriented institutions and EU pharma companies.

Priority 3: strengthen regulatory frameworks

- a. strengthening the institutional frameworks for national and regional regulatory systems (e.g., registration and marketing authorisation, licensing, inspection and market surveillance and control).
- b. strengthening mechanisms and platforms for regionally standardised system based on harmonisation, regulatory convergence, and recognition, via the existing National Regulatory Authority of Regional Reference.
- c. Potentially expansion to the WHO pre-qualification programme.

GUYANA

GGIA Outcome: Development and manufacturing of health products

Key priorities:

- 1- Support and reinforce opportunities for skills transfer with all EU based Pharma value chain stakeholders (public and private actors in academia, health delivery, manufacturing, distribution, importers)
 - a. Applied research and product development, in collaboration with EU firms and institutions,
 - b. Health service delivery, building on existing – successful- experience in organ transplant,
 - c. Collaboration in training of health workforce, in line with national Human Resources for Health (HRH) national strategy and training plans, promoting schemes of public-private partnerships for accrued efficiency (including public subsidies schemes with support from EU and EUMS)
- 2- Supporting national efforts to reinforce a conducive business environment, including:
 - a. management of the national health system (governance), identifying investment opportunities for local and EU private sector firms (outsourcing and partnerships).
 - b. upgrade the Guyana National Regulatory Agency to Maturity level 3 (following the model of cooperation with Rwanda), to lay the grounds to promote private sector investment.

This action includes five grants, two of which have a regional scope and three are earmarked for Guyana, responding to specific national needs in the context of a rapidly changing environment (per capita health expenditure has drastically increased from 158 USD/person in 2000, to 1,071 USD/person in 2020)¹. The first regional grant would involve building up on the initiated collaboration with the EU MS regulatory authorities and the EMA (European Medicines Agency) toward strengthening the institutional frameworks for national and regional regulatory systems to enhance the role of medical product regulators through clear and comprehensive legal bases for minimum functions related to registration and marketing authorisation, licensing, inspection and market surveillance and control. The collaboration would complement the intervention of PAHO on Equitable access to health technologies and local manufacturing capacities in Latin America and the Caribbean (LAC).

1.3 Zone benefitting from the Action

The Action shall be carried out in the Caribbean, with special focus on Barbados and Guyana, and with Mexico and Cuba for triangular cooperation initiatives, as pertinent.

¹ Source: [Current health expenditure per capita, PPP \(current international \\$\) - Guyana | Data \(worldbank.org\)](https://data.worldbank.org/SH.SVVS.SRVS.CV.GY), Accessed on April 19, 2024.

2 RATIONALE

2.1 Context

The European Union – Latin American and the Caribbean (EU-LAC) partnership on health resilience and vaccine production initiative, signed by President von der Leyen and Spanish President Sanchez in June of 2022 aims to foster cooperation in research and development, technology transfer, regulatory strengthening, and private sector involvement.

Through this the EU seeks to promote particular interest in: Regulatory harmonisation and particularly promotion of reliance on EU regulatory standards; Access to primary research and cooperation on applied research; creation of investment opportunity for EU private sector. These priorities align with CELAC's "Plan for self-sufficiency in health matters in Latin America and the Caribbean " which underscores the strategic approach to strengthening capacities for producing and distributing vaccines and medicines, with support from ECLAC and PAHO.

The initiative is anchored in a seven-component roadmap addressing vaccine manufacturing, regional supply chains, regulatory systems, procurement processes, scientific collaboration, pandemic preparedness, and health-related areas.

Further, in Latin America and the Caribbean, the Partnership on manufacturing vaccines, medicines and health technologies and strengthening health resilience in Latin America provides an entry point for Global Gateway support where first actions would focus on private-sector engagement, supply chains and access to finance; technology transfer, research and innovation; and regulatory frameworks and the enabling environment.

This action would additionally be complementary to the action, "Equitable access to health technologies and local manufacturing capacities in Latin America and the Caribbean (LAC)", signed with the Pan American Health Organisation (PAHO) in mid-2023. The objectives of Improved conditions for successful technology transferring and knowledge sharing in Latin America and the Caribbean and Regulatory systems for health technologies strengthened by advancing networks, regulatory convergence, harmonization, and the use of reliance mechanisms in Latin America and the Caribbean are aligned with the efforts in this action.

There is the goal that spill on activities contribute to the EU-LAC Global Gateway Investment Agenda "Health systems resilience and the digital transformation of health facilities" centred in Barbados. The goal is to foster an environment that promotes innovation and investment, and facilitates resilient and equitable access to health products responding to health priorities. In a best case scenario, the actions will be combined with EFSD+ actions in cooperation with EU private sector operators², for example the aforementioned Global Gateway initiative managed by the EIB and the Gates Foundation Accelerating Human Development (HDX) facilitates investment in the healthcare sector, particularly to improve manufacturing capacities. It covers three investment products, including corporate loans, venture loans and volume/procurement guarantees. These investments are matched by the Bill & Melinda Gates Foundation with new health investments and grants.

The three priorities addressed by this action in support of the roadmap for the Global Gateway Investment Agenda in the Caribbean are: regulatory strengthening in the Caribbean region; applied research, technology transfer and EU private sector investment; and, creating an enabling environment for pharmaceutical production through skills development of related professional and technical capacities, possibly by creating networks with regional academic institutions and EU based institutions.

A regionally important initiative, the "Pharmaceutical Equity for Global Public Health" initiative was launched jointly by the Prime Minister of Barbados, the President of the Republic of Guyana and the President of Rwanda

² There are 2 EFSD+ Open Architecture PIPs: (1) FMO/Cardano First Mover Health Investors Fund where LAC has EUR 7.5M in guarantee capacity; 2) EIB/Gates Foundation Human Development which LAC having a guarantee capacity of EUR 20M. For both PIPs 6 priority countries were identified, namely **Barbados**, Colombia, **Costa Rica**, Ecuador, El Salvador and **Mexico**. For further information: [European Fund for Sustainable Development Plus - European Commission \(europa.eu\)](https://www.efsd.europa.eu/). Each PIP will also benefit of a TA allocation of about 5%, meaning EUR 1M TA with the EIB and EUR 0,375M from FMO/Cardano.

in November 2022 in the presence of the President of the European Commission, Ursula von der Leyen, the Director General of WHO, the President of the European Investment Bank and the head of the Africa CDC.

The experiences of the territories in the Caribbean, particularly the CARICOM grouping during Covid-19 pandemic highlighted the limitations of the existing global pharmaceutical industry. The desire to build the pharmaceutical industry in Barbados and Guyana is in part a response to the trauma of the pandemic when both countries as well as the broader Caribbean region were unable to access sufficient COVID19 vaccines and experienced significant disruption to their health supply chain.

Having local pharmaceutical industry capabilities is seen to ensure that the countries, and the region at large are not so vulnerable in the event of a future pandemic. The concentration of R&D and manufacturing capabilities in the Global North, India and China was seen as a factor that contributed to vaccine inequity and has prompted renewed efforts to diversify pharmaceutical industry capabilities.

This initiative aims to serve the shared interest of Latin American and Caribbean leaders in enhancing their health systems and promoting local manufacturing capacities. The diversity of the Caribbean region will necessitate an approach that supports the ambitions of countries that are forging ahead such as Barbados and Guyana previously mentioned and balances with complementary actions in less advanced countries such as the Eastern Caribbean States.

A regional Caribbean Regulatory Service (CRS) hosted by the Caribbean Public Health Agency (CARPHA) exists. Countries voluntarily follow the advice especially in the context of market authorisations where stock-outs of essential medical products are common. Enhancing the profile of the CRS both legally and operationally could increase the support for these countries where gaps exist. This will have the potential to allow for increased protection of the citizens of the entire region.

In October 2023 a workshop was hosted by the European Union Delegations in Guyana and Barbados in collaboration with the Government of Guyana and CARPHA. This led to a better understanding on both sides of what would be needed in the area of regulation to advance on the proposed partnership in health, with a particular view on facilitating EU investment in the region.

A high-level study visit in February 2024 to institutions with notable applied research and tech transfer capacity across countries in Europe (Germany, Belgium, the Netherlands and France) allowed for the consideration of various tech transfer models and the integration of academia, private sector and business enablers for the industry within the region. The visit, with participation of the Minister of Health for Guyana, top academics from the Faculties of Medicine and Science and Medical Studies, senior officials of the investment promotion agency and export development agencies of Barbados as well as the Prime Minister's Office, set the agenda for continued collaboration with European institutions specialising in applied science, technology transfer offices, and networks supporting and managing innovation. Following this study tour, Barbados has contacted a few of the institutions visited with the ambition of procuring technologies from start-up companies, partnering with notable academic institutions for collaboration in applied research and inviting key persons in the field of biotechnology research to help with the establishment of programmes for innovation in the sector.

While the aforementioned EU-financed programmes by the the European Investment Bank on the reform of health systems in Barbados and the blending operation with the Inter-American Development Bank (IADB) for digitalisation of health systems are ongoing, activities supporting pharmaceutical production can be expanded. Both countries seek to diversify their economies. Guyana has identified the pharmaceutical industry as a priority as it looks to expand its manufacturing sector, and Barbados has identified life science industries and pharmaceutical manufacturing as it seeks to move beyond a service dominated economy.

The Guyana window aims at supporting the country not only in the development and manufacturing of health products, including vaccines, pharmaceuticals, and health sector equipment, but also to strengthen the health system governance, workforce skills and potentially the extension of the present organ transplant programme. Guyana is striving to expand its pharmaceutical industry to become a regional vaccine manufacturing hub and health care hub for the Caribbean. With this ambition, the desire to collaborate on applied research such as clinical trials and innovation in healthcare management has been expressed.

2.2 Problem Analysis

In early 2023 a study on the environment in Barbados and Guyana was carried out by the HISP Knowledge hub on Health, Social Protection and Inequalities. The main objective of the Scoping Mission for Barbados and Guyana for Pharmaceutical and Vaccine manufacturing and Development was to undertake an assessment of the enabling environment in Barbados and Guyana, in the context of the potential development and manufacturing for the pharmaceutical and vaccine sectors. The study was carried out by experts in the pharmaceutical regulatory industry, bio manufacturing and industrial business development.

While an overview of the structure of existing pharmaceutical industry in the two territories was generated, a deeper dive into specific areas was also carried out. An assessment of the frameworks for regulatory oversight for pharmaceuticals in each country looked at the maturity of both the regional and national regulatory agencies, with the ability to adequately regulate products manufactured locally.

Secondly, an investigation of the enabling environment for development of the industry in terms of investment incentives, availability of financing, government policy and legislative factors was assessed. Investment of EU interests would necessarily have to take many factors into account to determine the competitive advantage of investment in the region.

Finally, the skills available for both production and regulation within the sector with the aim of collaboration between universities and specialised laboratories for Research & Development, innovation and product development were assessed. Potential for triangular cooperation between the EU and Africa and the Caribbean in skills development and knowledge sharing for pharmaceutical and vaccine development was also considered. The output of this study was a SWOT analysis that provided a starting point for the EU interventions proposed in this document.

The recommendations resulting from the study with relevance to the EU cooperation were as follows.

In the framework of regulatory strengthening.

- The development of institutional development plans for the NRAs in Guyana and Barbados taking into consideration the ambitions of those countries.
- Mobilization of experts from European agencies and firms to support joint activities and training activities as well as to develop national frameworks supportive of a reliance approach. The experience of the twinning done in Rwanda is highly relevant given the agreement on Pharmaceutical Equity established with Barbados, Guyana in November 2022.
- Training in Good Manufacturing Practices (GMP) for the industry will be required. This could come via a ‘regulatory route’ or via industrial collaboration, which could mobilise EU expertise.

As a follow up to the recommendations above, a TAIEX organised Regional Workshop on EU-Caribbean Regulatory Systems for health products was held in Guyana in October 2023. The expert offered some recommendations based on the discussions held between national regulators from Guyana, Barbados and other Caribbean countries, including CRS.

In the context of expanding local production, an adequate environment to regulate medical products and ensure appropriate oversight is required. This was clearly evident from the presentations made at the workshop. In particular, an exploratory study of the needs in the region would help to define an operational strategy for regulation in the region and define clearly the needs of national and regional regulatory bodies was recommended.

The twinning experience in Rwanda was highly appreciated by Caribbean regulators and more clarity of the needs in the region has been gained in the meantime through collaboration with PAHO/WHO (assessments) and the application of the White Book for regulatory strengthening in Barbados and Guyana, with the aim to reach Maturity level 3 (from level 1 in both cases).

Measures are as well undergoing to strengthen regulatory oversight capacity, in partnership with PAHO and promoting joint inspections.

In the Caribbean, there is ongoing EU collaboration with CARPHA and PAHO to strengthen disease surveillance and health security. The EU recent experience with joint procurement and advance purchase agreements might be as well a model for LAC countries, and there is already an incipient EU-financed initiative in Central America on pooled procurement.

In considering the development of an environment that promotes innovation and investment, and facilitates resilient and equitable access to health products, while responding to health priorities, it was acknowledged that the area of knowledge transfer and best practices would need to be developed.

As a result, in February 2024 a Study Visit to several centres of excellence in Europe was held. These largely combined academic institutions, spin-offs, science and business parks, medium and larger companies, forming an ecosystem for valorising knowledge and facilitating the transfer of ideas from the research to the commercial realm. Barbados has invested in the development of a life sciences industry and has made available a Life Sciences Park where industry is provided with services that include property rental, technical assistance and business facilitation.

Following this study tour, Barbados has contacted several institutions visited with the ambition of procuring technologies from start-up companies, partnering with notable academic institutions for collaboration in applied research and inviting key persons in the field of biotechnology research to help with the establishment of programmes for innovation in the sector.

As a result, this action anticipates the strengthening of academic centres and support for innovation management in the medical and science programmes of Caribbean tertiary institutions. Additional partnerships between academic and applied research programmes for joint research as well as opportunities for specialized training and capacity building through exchanges of students, professors and academic departments are also on the table for consideration. This should be done through the development of partnerships between European and Caribbean institutions and firms that should facilitate direct exchange, also in terms of innovation by private sector actors.

An effective know-how and technology transfer will be fundamental to achieve the objective of the action.

In the specific case of Guyana, President Ali and Minister of Health Frank Anthony are leading the initiative to transform the country in a pharmaceutical and health service regional hub. They have specifically requested stronger EU involvement including presence of EU companies. Minister of Health has formally requested EU support in supporting the National Regulatory Agency of Guyana to reach Maturity Level 3 within the next three years, following the Rwanda-EU cooperation model. This is seen as a precondition for a sound legal framework that will foster foreign manufacturing companies to invest in the country. The Minister also has requested that the visiting EU experts (from 3 EU national regulatory agencies) comment and review the draft legislation on pharmaceutical products prepared by PAHO.

In terms of Guyana's ambitious plan for a complete overhaul of its health system, Government of Guyana has specifically requested EU support in providing training for hospital management, medical staff (doctor and nurses), research, digitalisation and reinforcement of their national transplant center.

Also, an EU company has been awarded 500mn. USD for the construction and equipment of two major hospitals, out of the thirteen planned. This opens further opportunities for European companies.

As expressed, there is a strong political drive in having an increased European presence, the Ministry has actively participated in the last two high level events held in Brussels, the Minister participated in the above referred study visit to key institutions in Germany, The Netherlands and Belgium and seeks to work closer with European companies and institutions alike. Following the first GGIA Economic mission in November 2023, the Delegation in Guyana intends to organise by late 2024, another event more focused on European companies in the pharma and health sector, as part of GG investment agenda.

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

Main stakeholders would be: Governments, Regulatory Agencies, regional institutions, entities for professional qualification at tertiary level, academic and research institutions, private sector operators.

3 DESCRIPTION OF THE ACTION

3.1 Objectives and Expected Outputs

The Overall Objective of this action is to support national and regional efforts to reinforce health resilience in the Caribbean region, in line with the GG Investment agenda for LAC.

The specific objectives (outcomes) are:

- 1- Collaboration with EUMS/EU regulatory agencies has contributed to strengthen both regulatory oversight of health system at country and regional level and open pathways to access to EU markets for local pharma and health firms in the future.
- 2- Partnerships with EU firms and institutions have contributed to improve professional and technical qualifications as well as institutional capacity (including national health systems management, with a particular focus in Guyana) for pharmaceutical production and export.
- 3- EU firms and institutions have supported the development and manufacturing of local medicines and health products, including vaccines, with a particular focus in Barbados and Guyana.

The Expected Outputs contributing to the corresponding Specific Objectives are:

- 1- Contributing to Outcome 1 (or Specific Objective 1):
 - a. EUMS/EU health regulatory agencies have designed and formalized partnerships to strengthen institutional frameworks for national and regional health regulatory systems (e.g., registration and marketing authorisation, licensing, inspection and market surveillance and control).
 - b. EUMS/EU health regulatory agencies are working with regional and national stakeholders to strengthen mechanisms and platforms based on harmonisation, regulatory convergence, reliance, and recognition (including, potentially, WHO pre-qualification programme).
 - c. EUMS health regulatory agencies have supported Guyana and Barbados' regulatory agency to reach maturity level 3, inspired by the EU's partnership in Rwanda with several EU regulatory agencies, including Lithuania's.
- 2- Contributing to Outcome 2 (or Specific Objective 2):
 - a. EU Pharma companies and public institutions are working, in tripartite modalities (public-private and research) with national authorities and small local pharma manufacturers to develop or reinforce professional and technical capacities (e.g., training for the application of Good Manufacturing Practices) that respond both to UHC goals and market needs.
 - b. EU pharma firms and other stakeholders of the pharma value chain (including importing firms) are supporting local pharma manufacturers improve market access to the EU of locally manufactured medical products, namely for compliance with EUM4All procedures.
 - c. EU institutions and firms have designed and established partnerships that contribute to strengthen research for local pharma manufacturers.
 - d. Collaboration with technology transfer offices, universities and research-oriented institutions and EU pharma companies has been established to promote greater market uptake of local pharma research.
- 3- Contributing to Outcome 3 (or Specific Objective 3)

- a. EU Pharma value chain stakeholders (public and private actors in academia, health delivery, manufacturing, distribution, importers) support and reinforce opportunities for skills transfer in the region, in Guyana and Barbados in particular.
- b. EU firms and institutions are contributing to local development of pharma products issued from applied (targeted) research.
- c. EU institutions support Guyana's efforts to improve health service delivery, building on existing – successful- experiences in organs' transplant.
- d. Collaboration mechanisms with EU and EUMS public and private institutions have been established for training of Guyana's health workforce, in line with national Human Resources for Health (HRH) national strategy and training plans, promoting schemes of public-private partnerships for accrued efficiency (including public subsidies schemes).
- e. Investment opportunities for local and EU private sector firms have been identified, designed, and supported through a GGIA scheme to reinforce conducive business environments in Barbados and Guyana, including management of Guyana's national health system (namely on governance).

3.2 Indicative Activities

Activities related to objective/ outcome 1: Collaboration with EUMS/EU regulatory agencies has contributed to strengthen both regulatory oversight of health system at country and regional level and access to EU markets for local pharma and health firms.

1. Support in review of and drafting of legislation on regulation of medicines and related pharmaceutical aspects, including legal act and regulations for regulatory agencies.
2. Support the registration and marketing authorisation processes.
3. Support the institutional strengthening of the regulatory agencies, including development of standard operating procedures and staff training modelled upon that of EU MS agencies.
4. Technical assistance for establishment of a reliance mechanism with identified regulators.
5. Technical assistance for establishment of harmonised regulatory systems (regional, EU and international standards)
6. Provision of technical assistance for the expansion of services of the regional regulatory services (example: regional inspections, market authorisations, etc.).

Activities related to objective/ outcome 2: Partnerships with EU firms and institutions have contributed to improve professional and technical qualifications as well as institutional capacity (including national health systems management) for pharmaceutical production and export.

1. Study exchanges for students, researchers and managers of applied science from the Caribbean with counterparts in Europe from public and private actors.
2. Technical assistance for inclusion of industry-informed courses at Caribbean institutions at both the technical and professional levels, such as training in GMP.
3. Attachments for doctoral and post-doctoral persons to entities for development of skills in applied science and research.
4. Health workforce training plans designed, based on market needs of the pharmaceutical and life sciences local industries and fully integrated onto national training plan for Human resources for health (aligned with National Health Strategies).

Activities related to objective/outcome 3: EU firms and institutions have supported the development and manufacturing of local medicines and health products, including vaccines, with a particular focus in Guyana.

1. Trade fair participation, b2b and matchmaking events between EU and Caribbean companies in the pharma, biotech and Life Sciences sector.
2. Roadshow of Caribbean actors to attract investment and business collaboration from EU.

3. Direct exchange between relevant institutions in Caribbean and EU.

Activities here will be complemented by other relevant instruments to facilitate private sector cooperation between the EU and the Caribbean, most concretely, support for (pre-)feasibility studies to be financed under the CCF and other relevant programmes, as well as support through EFSD+ instruments, blending and guarantees, for concrete investment projects such as the aforementioned EIB/Gates Foundation Global Gateway initiative Accelerating Human Development (HDX).

3.3 Mainstreaming

This action promotes resilience as a primary objective. This is particularly in reference to the health sector and relates directly to the supply of essential medicines, vaccines, therapeutics and other medical products. Through the actions envisaged, the promotion of at least two (2) interrelated sustainable development goals will be achieved.

These include the SDG 3 Good Health and Well-Being, SDG 10 Reduced Inequalities. While health systems in the countries of the region will be improved, especially through the regulatory framework for access to safe medical products, inequality of access to medical products between countries will also be addressed.

Environmental Protection & Climate Change

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

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

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

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

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

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

Gender equality and empowerment of women and girls

As per the OECD Gender DAC codes identified in section 1.1, this action is labelled as G1. This implies that the action is considered somewhat relevant for gender equality. In the Caribbean region there is strong dominance of women in fields of tertiary education and within the high skilled labour force. Once out of the education system, however, girls are confronted by challenges such as lack of childcare support, harassment, and sometimes even violence. Men in the Caribbean are more likely to be employed and, they usually make more money than women. Women in Dominica and Jamaica, for instance, earn roughly 85 cents for every dollar earned by men. Given this dynamic, the action is not seen as having the potential to erode the gains of women in the academic field, the regulatory environment nor within the private sector, but to contribute to expanding areas for participation of women.

Human Rights

The activities are designed to 'leave no one behind' in line with the human rights-based approach. The action ensures that groups with specific needs (women, persons with disabilities, youth, among other groups) will take an active part in demanding transparency and accountability from their leaders, participate in decision-making processes related to the delivery of local services and access a more friendly and efficient justice delivery system. To this end, a consultation process with right-holders about their needs and aspirations will be carried out along the different stages of the project's cycle. The consultations will promote and ensure the participation and voice of women, including more vulnerable groups such as single women, the elderly and young women, LGBTQI+ and persons with disabilities.

An accountability mechanism will be in place for people and communities who believe that they have been, or are likely to be, harmed by the Action, and access to information will be ensured.

Disability

As per OECD Disability DAC codes identified in section 1.1, this action is labelled as D0. This implies that the action is not considered relevant for inclusion of persons with disabilities.

Reduction of inequalities

The COVID-19 pandemic had the effect of highlighting the inequalities of access to medical products and vaccines in low and middle income countries. This action is formulated as a direct response to ensure that low and middle income countries in the CARICOM region are in a position to produce medical products in the event that similar events occur in the future. The inequality reduction will take place at a regional and country level and be compared against the access to vaccines and medical products in 2021.

Democracy

Most territories in the region are functional multiparty parliamentary democracies. The main stakeholders will be: Governments, Regulatory Agencies, regional institutions, entities for professional qualification at tertiary level, academic and research institutions, private sector operators. As such, the upholding of democracy will be ensured through the involvement of diverse stakeholders with a common vision for enhancing the health systems and facilitating economic growth

Conflict sensitivity, peace and resilience

The action strengthens resilience of the region by reinforcement of the health care system. Strengthened resilience will also result from the activities focused on skills development and capacity building for technology transfer. It should be highlighted that the action will contribute to enhancing the region overall resilience, in terms of being better prepared to protect its population against different diseases,

Disaster Risk Reduction

N/A

3.4 Risks and Lessons Learnt

Category	Risks	Likelihood (High/ Medium/ Low)	Impact (High/ Medium/ Low)	Mitigating measures
Legality and regulatory aspects	Lack of progress on legislation related to regulatory frameworks	M	H	Provide complementary support from facilities and constant coordination with PAHO.
Legality and regulatory aspects	Limited capacity of regulatory authorities	M	H	Provide training, coaching and technical assistance.

External environment	Limited private sector interest in investment in pharmaceutical manufacturing	M	H	Facilitate business to business meetings and missions between manufacturers
People and organisation	Lack of political leadership and commitment to drive process forward	L	H	Constant policy dialogue.

Lessons Learnt:

Lessons learnt can be drawn as one example from the Programme of Support for Health System Strengthening for Prevention and Control of Outbreaks of Communicable Diseases in the Caribbean, the Regional Health Security programme led by CARPHA. This programme deals with ensuring health security as a regional bloc. These have shown that:

- Continuous consultation with all partners must be strong and effective in order to ensure the implementation of relevant activities, particularly with the regular meeting at bilateral level, the regular dialogue with CARPHA CRS as well as the at CARICOM level in the framework of the Council for Human and Social Development (COHSOD). The current situation in Barbados in this particular sector constitutes a good practice to be continued with regular consultations between the different public entities involved (Ministry of Health, Barbados Drug Service, Export Barbados, Invest Barbados, University of the West Indies, private sector, donors, particularly EU and PAHO) and even a regular information exchange beyond. The regular consultation creates transparency, a higher level of alignment, allows for coordination, division of labour and direct cooperation.
- Efforts must be made to continuously engage and seek opportunities to involve like-minded institutions in the EU. For this, direct contracts with EU actors, namely EU regulatory agencies, academic and research will be a primary vehicle. Moreover, there will be concrete activities such as study visits, trade fair participation, roadshows, participation in scientific events as well as exchange programmes that will serve this purpose.
- Given the high dynamic in the sector and the commitment of the partner governments to advance in these areas, the EU and its programmes must be able to respond and adapt quickly to the rapidly evolving situation in the partner countries.

Another positive experience from past actions is to work in a complementary way and not in silos. In this sense, the present action should benefit from other actions and instruments in support of the GGIA. **The present action acts as an enabler** of the sister action for private sector development, working to reinforce a more conducive and stable business environment, improving regulatory frameworks, training adequate workforce for the industry and promoting EU private sector investments by derisking operations in the sectors of biotechnology, pharmaceutical and life/sciences. This action clears **a pathway to the mobilisation of private sector investments**, through EFSD+, as well as other EU-financed programmes for private sector investment, the Caribbean Cooperation Facility and others.

It should also benefit from the partnerships the EUDEL has been building with local, regional and European stakeholders that allow to the EUDEL to act as door opener and connector of different actors as well as the dialogues organised by headquarters, such as the High Level Meeting on Health in March 2024 or similar events.

3.5 The Intervention Logic

The underlying intervention logic for this action is that the EU will support the **development of key drivers** needed to establish local manufacturing capacity and enhance health system resilience in the Caribbean region and to **reinforce the health care delivery system in Guyana**.

If an **adequate regulatory framework** exists in countries aiming for local pharmaceutical manufacture; with a cadre of persons **with available skills and capacity** in providing research and production services; backed by a **business-enabling environment** that is responsive to the markets and inspires confidence **to invest** in the pharmaceutical industry, then the resilience of the health sector will be improved and local pharmaceutical manufacturing facilitated.

Addressing these key areas will contribute to improve the health care systems to be able to deliver better services.

The achievement of these objectives relies on

- Continued political will of actors in the region, translated in evidence-based national strategies and fully funded operational plans,
- Alignment of countries' partners in the region to national and regional priorities
- Proper monitoring of priorities through an agreed set of indicators, defined and communicated through the preparation and dissemination of annual operational plans at national dialogue/ coordination fora, led by Governments,
- Fully funded and well-functioning health information systems that will inform progress made towards priorities, as well as inform, on a regular basis, changes that require course correction,
- Well-defined publicly communicated and controlled for, standard procedures for procurement of private sector services for health, including supply of medicines and health products, health services, including management and administrative services,
- A clear common vision of national governments and private sector health firms of the need to achieve equitable access to Universal health care,
- The ability of countries to attract investment in the sector.

3.6 Logical Framework Matrix

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	Support national and regional efforts to reinforce health resilience in the Caribbean region, in line with the GG Investment agenda for LAC	<p>1 Country Universal Health Coverage Index (Regional and per country)</p> <p>2 Number of new private sector firms investing in Pharmaceutical sector/value chain in the region and per country</p> <p>3 Increased and diversified trade in medical goods and services within the region and with the EU</p> <p>4 Value added of sector/value chain (% GDP)</p>	<p>1 (2018) TBC</p> <p>1 (2022) 2</p> <p>2 TBD</p> <p>3 TBD</p>	<p>1 2027 TBC</p> <p>2 >3 2027</p> <p>3 TBD</p> <p>4 TBD</p>	<p>WHO and WB health data</p> <p>Ministry of Health reports</p> <p>Chambers of Commerce reports</p> <p>Ministry of Trade</p> <p>EUDEL</p>	<i>Not applicable</i>
Outcome 1	Collaboration with EUMS/EU regulatory agencies has contributed to strengthen both regulatory oversight of health system at country and regional level and open pathways to access to EU markets for local pharma and health firms in the future	<p>1.1 Partnerships between EUMS/ EU health regulatory agencies and Caribbean NRA are operational</p> <p>1.2 Work to strengthen mechanisms and platforms for reliance and regulatory frameworks, strengthened with EU/EUMS support is ongoing.</p> <p>1.3 Partnership with EUMS on NRA strengthening has been formed and is operational</p>	<p>1.1</p> <p>1.2</p> <p>1.3</p>	<p>1.1</p> <p>1.2</p> <p>1.3</p>	<p>MoU</p> <p>Partnerships agreements</p> <p>Platforms meetings PVs</p> <p>Reports from Ministries of Health</p>	<p>1. Continued budgetary increase for the NRAs across countries, per identified needs.</p> <p>2. Adequate staffing of NRAs with qualified well-paid human resources</p>
Outcome 2	Partnerships with EU firms and institutions have contributed to improve professional and technical qualifications as well as institutional capacity (including national health	2.1 Collaboration between EU Pharma companies and institutions in skills reinforcement for compliance to EU	2.1	2.1	Reports from academic institutions	HRH strategies exist, with clear evidence-

	<p>systems management, with a particular focus in Barbados and Guyana) for pharmaceutical production and export.</p>	<p>and international standards is underway.</p> <p>2.2 Training programmes for resilience in the health workforce with specialised institutions are established</p> <p>2.3 Partnerships between EU institutions or firms have created opportunities for joint applied (targeted) research and product development</p> <p>Ratio of female to male who have benefitted from Vocational Education and Training / Skills development and other active labour market programmes leading to jobs (GAPIII)</p>	<p>2.2</p> <p>2.3</p>	<p>2.2</p> <p>2.3</p>		<p>based fully funded priorities</p> <p>2. HRH strategies include a training plan for HRH</p> <p>3. Governments identify and share financial and skills gaps</p>
<p>Outcome 3</p>	<p>EU firms and institutions have supported the development and manufacturing of local medicines and health products, including vaccines, with a particular focus in Barbados and Guyana.</p>	<p>3.1 Training programmes for resilience in the health workforce with specialised institutions are established</p> <p>3.2 . Number of research projects that are linked to product development)</p>	<p>3.1</p> <p>3.2</p>	<p>3.1</p> <p>3.2</p>	<p>Triangular cooperation partnerships or MoUs</p> <p>Registry of research projects (MoH and international platforms)</p> <p>Published papers from local researchers</p> <p>Reports from companies</p>	<p>Government is working towards improving business environment, particularly in the pharma/ life science sector</p> <p>2. EU pharma and life sciences firms are interested in partnering with Caribbean firms and institutions</p>

					doing business in the sector	
Output 1.1	1.1 EUMS/EU health regulatory agencies have designed and formalized partnerships to strengthen institutional frameworks for national and regional health regulatory systems (e.g., registration and marketing authorisation, licensing, inspection and market surveillance	1.1.1 Agreement on most appropriate and relevant institutional framework modeled on EUMS has been identified and being worked on 1.1.2 Structure of the regulatory authority allows for the minimum number of recommended functions being performed by a national authority as outlined by PANDRH (GY & BB)	1.1.1 1.1.2	1.1.1 1.1.2	Government budget estimates	Continued and adequate political will and economic resources support the transformation of the regulatory authority
Output 1.2	1.2 EUMS/EU health regulatory agencies are working with regional and national stakeholders to strengthen mechanisms and platforms based on harmonisation, regulatory convergence, reliance, and recognition (including, potentially, WHO pre-qualification programme).	1.2.1 Formal agreements between regional and national regulatory authorities and authorities of EUMS/ EU for reliance and recognition have been established (GY&BB) 1.2.2 Platforms for information exchange among national and regional regulatory authorities exist	1.2.1 1.2.2	1.2.1 1.2.2	Monitoring reports	Caribbean countries accept that reliance is the most suitable method for regulatory framework development in light of the limited resources that are available to them
Output 1.3	1.33 EUMS health regulatory agencies have supported Guyana and Barbados' regulatory agency to reach maturity level 3, replicating the model used in the EU's partnership in Rwanda with Lithuania's regulatory agency.	1.3.1 Work to strengthen essential functions for NRAs to achieve Maturity level 3 is ongoing (GY & BB)			Reports from CARPHA	Countries that are less likely to manufacture medical products are interested in the value offered by the platforms hosted by CRS
Output 2.1	2.1 EU Pharma companies and public institutions are working, in tripartite modalities (public-private and research) with national authorities and small local pharma manufacturers to develop or reinforce professional and	2.1.1 Number of persons in the sector upskilled for particular roles in industrial/ pharmaceutical manufacturing (GY & BB)	2.1.1 2.1.2	2.1.1 2.1.2	Reports by existing businesses Reports by Investment	Stakeholders are willing and able to participate in initiatives to reinforce

	technical capacities (e.g., training for the application of Good Manufacturing Practices) that respond both to UHC goals and market needs	2.1.2 Number of specialised areas with workers being trained (GY&BB)			promotion and Industrial development agencies	professional and technical skills Opportunities to enhance professional and technical skills are widely promoted to industry stakeholders as well as other interested persons who may be seeking entry into the sector
Output 2.2	2.2 EU pharma firms and other stakeholders of the pharma value chain (including importing firms) are supporting local pharma manufacturers improve market access to the EU of locally manufactured medical products, namely for compliance with EUM4All procedures.	2.2.1 Number of collaborations between EU actors in the value chain and local manufacturers (BB& GY)	2.2.1 2.2.2	2.2.1 2.2.2		EU and local firms are able to access funding via complementary avenues to pursue compliance with global standards for manufacturing
Output 2.3	2.3 EU institutions and firms have designed and established partnerships that contribute to strengthen research for local pharma manufacturers	2.3.1 Joint research programmes in pharma and life sciences research being undertaken			Reports from the Ministry of Health in Guyana	There is mutual interest in the development of joint research programmes
Output 2.4	2.4 Collaboration with technology transfer offices, universities and research-oriented institutions and EU pharma companies has been established to promote greater market uptake of local pharma research	2.4.1 Number of projects that have commenced and made an attempt at valorisation through tech transfer offices in Barbados				The network approach to technological transfer, innovation management and valorisation of applied research

						is supported ; Funding for the development of tech transfer model is made available
Output 3.1	3.1 EU Pharma value chain stakeholders (public and private actors in academia, health delivery, manufacturing, distribution, importers) support and reinforce opportunities for skills transfer in the region (including Cuba and Mexico), in Guyana and Barbados in particular	3.1.1 Number of new collaborations between pharma manufacturing stakeholders and pharma and life science actors in Barbados, the region and Guyana including tertiary level institutions	TBD TBD TBD		Reports from Investment promotion agencies and chambers of commerce	Stakeholders in both Guyana and Barbados seize the opportunities to develop or enhance skills in the sector
Output 3.2	3.2 EU firms and institutions are contributing to local development of pharma products issued from applied research	3.2.1 Presence of collaborations between EU actors in the value chain and local manufacturers in the development of enhanced or new pharma products	TBD	TBD	Reports from the Ministry of Health O	Joint research between EU actors and local researchers is adequately promoted and funded
Output 3.3	3.3 EU institutions support Guyana's efforts to improve health service delivery, building on existing – successful- experiences in organs' transplant	3.3.1 National Organ transplant services are expanded	TBD	TBD		
Output 3.4	3.4 Collaboration mechanisms with EU and EUMS public and private institutions have been established for training of Guyana's health workforce, in line with national Human Resources for Health (HRH) national strategy and training plans, promoting schemes of public-private partnerships for accrued efficiency (including public subsidies schemes).	3.4.1 Number of persons trained as a result of agreements between training institutions in EUMS and the Government of Guyana	TBD	TBD	Reports from the Ministry of Health in Guyana MoU signed, reports from EU and healthcare institutions, and official	National Strategy on HRH exists There is a Training plan for HRH in Guyana that responds to

					government statistics.	medium term needs
Output 3.5	3.5 Investment opportunities for local and EU private sector firms have been identified, designed, and supported through a GGIA scheme to reinforce conducive business environments in Barbados and Guyana, including management of Guyana's national health system (namely on governance).	3.5.1 New Investments in Guyana and Barbados that support the development of medical products and provide opportunities for private sector led growth in the health sector				Multiple avenues for investment are promoted and supported by both the EU and Government of Guyana through their respective investment promotion initiatives

4 IMPLEMENTATION ARRANGEMENTS

4.1 Financing Agreement

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

4.2 Indicative Implementation Period

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

4.3.1 Direct Management (Grants)

Grants: (direct management)

There will be several grants for the following purposes and amounts:

1. One regional grant for the strengthening of regulatory systems (EUR 2 million).
2. One regional grant for skills development and technology transfer (EUR 3 million).
3. Several grants for the strengthening of healthcare delivery in Guyana (EUR 3.9 million).

It is planned to launch the respective call for proposals in different moments due to different factors such as urgency for beneficiaries, state of preparation, availability of commitment credits etc.: i) Grant Strengthening of regulatory systems would be either awarded to a consortium of EU regulatory agencies due to their very specific characteristics including exclusive legal competence for the regulation of medicines in their respective countries or through a call for proposals under a suspensive clause before official adoption of the financing decision; ii) grant skills development and technology transfer end of 2024/beginning 2025; iii) Grants healthcare delivery Guyana in 2025/2026. However, in case that these timeframes are adjusted and there is a chance to publish different call for proposals at the same time, a joint call for proposal containing different lots would be launched.

Grant 1: Strengthening regulatory systems (EUR 2 million). (direct management)

(a) Purpose of the grant(s)

Specific objective or Outcome 1: Collaboration with EUMS/EU regulatory agencies to strengthen both regulatory oversight of health system at country and regional level and open pathways to access to EU markets for local pharma and health firms in the future.

(b) Type of applicants targeted

The applicants targeted would be primarily European regulatory authorities and European cooperation agencies, but also local authorities, public bodies, international organisations if duly justified by the proposal.

Participation of consortia of EU Member State regulatory authorities that include actors that are part of the Twinning arrangement with Rwanda and EU Member States for the establishment of the Rwanda Food and Drug Agency would be encouraged. These consortia should be formed with due consideration to the embryonic nature of the actions proposed, the existing human resource capacity of the beneficiary authorities and the size of the populations to be served. It would be preferred for a combination of more established authorities and authorities in accession countries make up these consortia so that a range of best practices suitable to the beneficiaries can be presented.

(c) Justification of a direct grant

Under the responsibility of the Commission's authorising officer responsible, the grant may be awarded without a call for proposals to a consortium of regulatory agencies for medicines that will be selected using the following criteria: Legal authority for the regulation of medicines in an EU Member State; experience in international cooperation on regulatory issues; experience with reliance systems in line with EMA and WHO regulations.

Under the responsibility of the Commission's authorising officer responsible, the recourse to an award of a grant without a call for proposals is justified because the Action falls within article 195 (f) of the Financial Regulation, i.e. " for activities with specific characteristics that require a particular type of body on account of its technical competence, its high degree of specialisation or its administrative powers, on condition that the activities concerned do not fall within the scope of a call for proposals". Only EU regulatory agencies possess the necessary highly specialised institutional knowledge based on their exclusive legal mandate to regulate medicines in their respective EU Member States and the legal and administrative power to allow to rely on them for the recognition of medicines.

As an alternative option it is also considered to launch a call for proposals under a suspensive clause that shall be authorised as of 1 May 2024 prior to the adoption of this Decision. This is justified because of the high political priority of the actions in the partner countries and for the EU. It would be important to be able to move forward to ensure that a European model of regulation can be first in place for consideration. The dialogue and work with the EU is well advanced thanks to the TAIEX actions. The strengthening of the regulatory systems is the main priority in this field for the partner countries and they are determined to advance quickly.

Grant 2: Skills Development and technology transfer (EUR 3 million). (direct management)

(a) Purpose of the grant(s)

Specific objective or Outcome 2: Partnerships with EU firms and institutions to improve professional and technical qualifications as well as institutional capacity (including national health systems management) for pharmaceutical production and export.

A call for proposals will be launched where operators or consortium of operators will be invited to provide services that fulfil the objectives indicated.

(b) Type of applicants targeted

The applicants targeted would be European firms, universities and institutes of applied research, public bodies, business support organisations, European cooperation agencies and international organisations.

As an alternative option it is also considered to award a grant without a call for proposal under the responsibility of the Commission's authorising officer responsible to a consortium of European universities and technology transfer centres that will be selected using the following criteria: At least 10 years of experience in applied research and technology transfer in an EU Member State; experience in international cooperation on technology transfer and cooperation on applied research. Under the responsibility of the Commission's authorising officer responsible, the recourse to an award of a grant without a call for proposals would be justified because the Action falls within article 195 (f) of the Financial Regulation, i.e. " for activities with specific characteristics that require a particular type of body on account of its technical competence, its

high degree of specialisation or its administrative powers, on condition that the activities concerned do not fall within the scope of a call for proposals”.

Grants 3: Strengthening of healthcare delivery in Guyana (EUR 3.9 million). (direct management)

(a) Purpose of the grant(s)

Specific Objective 3 or Outcome 3: EU firms and institutions to support the development and manufacturing of local medicines and health products, including vaccines, with a particular focus in Barbados and Guyana.

A call for proposals will be launched where operators or consortium of operators will be invited to provide services that fulfil all the objectives indicated. It is planned to launch a call with several lots addressing i) health system governance, ii) workforce qualification in the health sector, including management skills and iii) organ transplants.

(b) Type of applicants targeted

The applicants targeted would be European public and private health care providers, specialised organisations in the field of organ transplants, universities and institutes of applied research, public bodies, business support organisations, European cooperation agencies and international organisations.

The part of the action under the budgetary envelope reserved for grants may, partially or totally and including where an entity is designated for receiving a grant without a call for proposals, be implemented in indirect management with an entity, which will be selected by the Commission’s services using the criteria defined above.

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

As an alternative implementation modality to the planned direct management via the part of the action under the budgetary envelope reserved for grants may, partially or totally be implemented in indirect management using the criteria in section 4.3.1 above.

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 components	EU contribution (amount in EUR)
Objective/ outcome 1: Collaboration with EUMS/EU regulatory agencies has contributed to strengthen both regulatory oversight of health system at country and regional level and open pathways to access to EU markets for local pharma and health firms in the future.	2,000,000
Grants (direct management) – cf. section 4.3.1	

Objective/ outcome 2: Partnerships with EU firms and institutions have contributed to improve professional and technical qualifications as well as institutional capacity (including national health systems management, with a particular focus in Barbados and Guyana) for pharmaceutical production and export.	3,000,000
Grants (direct management)	
Objective/ outcome 3 : EU firms and institutions have supported the development and manufacturing of local medicines and health products, including vaccines, with a particular focus in Guyana.	3,900,000
Grants (direct management) cf. section 4.3.1	
Grants – total of the several grants foreseen under section 4.3.1	8,900,000
Evaluation – cf. section 5.2 Audit – cf. section 5.3	may be covered by another Decision
Contingencies	0
Totals	8,900,000

4.6 Organisational Set-up and Responsibilities

<p>The European Commission, through DG INTPA (cooperation section) in the EU Delegations of Barbados and Guyana, is responsible for the management of this action. The action will be managed by both the EU Delegations in a coordinated manner, with each one being in the lead for actions falling under its respective geographical responsibility, i.e. the EU Delegation to Barbados, the Eastern Caribbean States and CARICOM/CARIFORUM will be in the lead for the two first grants targeting objectives 1-3 whereas the Delegation to Guyana and Suriname will be responsible for the contracts related to objective 4. Moreover, some specific responsibilities may include:</p> <p><u>EU Delegations</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> Ensuring programme alignment with EU strategies and policies mainly on national levels <input type="checkbox"/> Ensuring synergies with other EU and MS financed actions in partner countries <input type="checkbox"/> Support the coordination of the Steering Committees (see below) <input type="checkbox"/> Ensure EU visibility in partner countries <input type="checkbox"/> Management of contracts with implementing agencies and organisations <input type="checkbox"/> Support the monitoring of results in partner countries <p><u>Implementing partners responsibilities:</u></p> <ul style="list-style-type: none"> <input type="checkbox"/> Ensuring that programme objectives and results are achieved as per agreed contracts <input type="checkbox"/> Ensure regular information exchange with other implementing agencies and organisations <input type="checkbox"/> Collection and dissemination of best practices <p>Programme Steering Committee</p> <p>The European Commission through the respective Delegations will chair the Steering Committees of the action, which will be organised at least once a year. The Steering Committee will provide direction to the programme implementation ensuring that the activities are consistent with the planned objectives and expected outcomes. Members of the Steering Committee include DG INTPA (both HQ and Delegations), other relevant actors from the European Commission, implementing partners and representatives from the partner countries and regional bodies. The steering committee will seek to facilitate the exchange of information and best practice and establish priorities and ensure the monitoring of these. A more detailed governance structure will be defined within the contracts of the implementing partners.</p> <p>As part of its prerogative of budget implementation and to safeguard the financial interests of the Union, the Commission may participate in the above governance structures set up for governing the implementation of the action and may sign or enter into joint declarations or statements, for the purpose of enhancing the visibility of the EU and its contribution to this action and ensuring effective coordination.</p>

4.7 Pre-conditions

Before the start of activities under this action, the European Commission through the respective Delegations will engage in discussions with the beneficiary organisations to determine the status of actions ongoing. The implementing partners must as a prerequisite engage with the partner countries to determine the status at that time before start of activities.

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).

The implementing partners will be responsible for data collection, analysis and monitoring. The data monitoring, analysis and collection will be implemented as an integral part of the activities executed by the implementing partners and will form a key component of the contractual arrangements. It is expected that key stakeholders identified and final beneficiaries of the actions undertaken in Barbados, Guyana and the region will be engaged for the provision and verification of data collected under the action.

All monitoring and reporting shall assess how well the action promotes the principle of gender equality which lies at the heart of this programme and takes a human rights-based approach and enables the rights of persons with disabilities including through strengthening inclusion and diversity. Data collected, where appropriate and possible, will be disaggregated by sex and age, and by disability if tenable.

5.2 Evaluation

Having regard to the importance of the action, an ex-post evaluation(s) may be carried out for this action or its components via independent consultants contracted by the Commission.

It will be carried out for accountability and learning purposes at various levels (including for policy revision), taking into account in particular the fact that the action is an important one for the region in the context of the Global Gateway Investment Agenda. The suitability and mode of implementation will be assessed to determine if the objectives of the GGIA are being complemented adequately.

The Commission shall inform the implementing partner at least 4 months in advance of the dates envisaged for the evaluation missions. The implementing partner shall collaborate efficiently and effectively with the evaluation experts, and inter alia provide them with all necessary information and documentation, as well as access to the project premises and activities.

The evaluation reports may be shared with the partners and other key stakeholders following the best practice of evaluation dissemination³. The implementing partner and the Commission shall analyse the conclusions and recommendations of the evaluations and, where appropriate, apply the necessary adjustments. In addition, all evaluations shall assess to what extent the Action is taking into account human rights-based approaches as well as whether and how the Action contributes to gender equality and women's empowerment and disability inclusion. The evaluation process will include expertise on human rights, disability and gender equality assessment.

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

5.3 Audit and Verifications

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

6 STRATEGIC COMMUNICATION AND PUBLIC DIPLOMACY

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

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

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

³ See best [practice of evaluation dissemination](#)

Appendix 1 REPORTING IN OPSYS

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

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

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

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

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

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

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

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