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

**ANNEX 3**

to the Commission Implementing Decision on the financing of the annual action plan in favour of Cuba for 2022

**Action Document for Support to Cuban biotechnological industry and investments towards Global Public Goods**

| **ANNUAL PLAN** |
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| This document constituting the annual work programme in the Article 110 (2) of the Financial Regulation, and action plans in the meaning of Article 23 of NDICI-Global Europe Regulation. |

# 1 SYNOPSIS

## 1.1 Action Summary Table

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| **1. Title**<br><br>**CRIS/OPSYS business reference**<br>**Basic Act** | Support to Cuban biotechnological industry and investments towards Global Public Goods<br>**CRIS nº: NDICI LA/2022/044-162 / OPSYS ACT-61520**<br>Financed under the Neighborhood, Development and International Cooperation Instrument (NDICI-Global Europe)/ Overseas Association Decision/European Instrument for International Nuclear Safety Cooperation Regulation |
| **2. Team Europe Initiative** | Yes : under the European Union – Latin America and Caribbean partnership on local manufacturing of vaccines, medicines and other health technologies, and strengthening health systems resilience.<br><br>The contribution of Member States, International Financing Institutions and implementing agencies is to be determined. |
| **3. Zone benefitting from the action** | Cuba |
| **4. Programming document** | Multiannual Indicative Programme (MIP) — EU-Cuba Cooperation 2021-2027 |
| **5. Link with relevant MIP (s) objectives/expected results** | This action is related to the second priority of the MIP 2021-2027 Modernisation of the Economy, by supporting the advanced Cuban biotechnological sector. Given its added value in exports and taking advantage of the presence already of some Cuban Bioindustry production plants and commercial offices in the EU, the action will contribute to open Cuban's economy and increase economic ties with Europe. Under the right conditions, there is potential for Cuban and European private sector engagement.<br>The action, as foreseen in the EU-Cuba MIP 2021-2027, will support the development and distribution, through multilateral mechanisms such as COVAX, of safe and effective vaccines, diagnostic and therapeutic products against Covid-19 and other priority health challenges.<br>The Action contributes to Specific objective 3 from MIP's Priority Area 2 ("Modernisation of the economy through maximizing the potential of all economic actors in key sectors"): |

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| | "Contribute to the development, production and distribution of safe and effective vaccines, diagnostic and therapeutic products against Covid-19 and other priority health challenges." |
| **PRIORITY AREAS AND SECTOR INFORMATION** | |
| **6. Priority Area (s), sectors** | 2 |
| **7. Sustainable Development Goals (SDGs)** | SDG 9: Industrial, innovation and infrastructure<br>SDG 3: Ensure healthy lives and promote well-being for all at all ages<br>The project has also an indirect impact on Sustainable Development Goals (SDGs) 17.6, 17.7, 17.8 and 17.11 of the 2030 Agenda. |
| **8 (a) DAC code (s)** | 32120 Industrial development<br>121 Health, general |
| **8 (b) Main Delivery Channel** | 41000 United Nations (UN) agency, fund or<br>11004 Other public entities in donor country (Member States agency to be confirmed) |
| **9. Interference of multilateral partners** | No |
| **10. Targets** | ☐ Migration<br>☐ Climate<br>☒ Social Inclusion and Human Development<br>☐ Gender<br>☐ Biodiversity<br>☐ Education<br>☐ Human Rights, Democracy and Governance |

| **11. Markers (from DAC form)** | **General policy objective** @ | **Not targeted** | **Significant objective** | **Main objective** |
|---|---|---|---|---|
| | Participation development/good governance | ☐ | ☒ | ☐ |
| | Aid to environment @ | ☒ | ☐ | ☐ |
| | Gender equality and women's and Girl's Empowerment | ☐ | ☒ | ☐ |
| | Trade development | ☐ | ☒ | ☐ |
| | Reproductive, maternal, newborn and child health | ☒ | ☐ | ☐ |
| | Disaster Risk Reduction @ | ☒ | ☐ | ☐ |
| | Inclusion of persons with Disabilities @ | ☒ | ☐ | ☐ |
| | Nutrition @ | ☒ | ☐ | ☐ |
| | **Rio Convention Markers** | **Not targeted** | **Significant objective** | **Main objective** |
| | Biological diversity @ | ☒ | ☐ | ☐ |

| | | | | |
|---|---|---|---|---|
| | Fighting desertification @ | ☒ | ☐ | ☐ |
| | Climate change mitigation @ | ☒ | ☐ | ☐ |
| | Climate change adaptation @ | ☒ | ☐ | ☐ |
| **12. Internal Markers and tags**: | **Policy objectives** | **Not targeted** | **Significant objective** | **Main objective** |
| | Digitalisation @<br>digital connections<br>digital governance<br>digital entrepreneurship<br>digital skills/literature<br>digital services | ☐ | ☒<br>☐<br>☒<br>☐<br>☐<br>☒ | ☐<br>☐<br>☐<br>☐<br>☐<br>☐ |
| | Connectivity @<br>transport<br>people2people<br>energy<br>digital connection | ☐ | ☒<br>☐<br>☐<br>☐<br>☒ | ☐<br>☐<br>☐<br>☐<br>☐ |
| | Migration @<br>(methodology for tagging under development) | ☒ | ☐ | ☐ |
| | Reduction of Inequalities<br>(methodology for marker and tagging under development) | ☐ | ☒ | ☐ |
| | COVID-19 | ☒ | ☐ | ☐ |
| **BUDGET INFORMATION** | | | | |
| **13. Amounts concerned** | Budget line (s) (article, item): BGUE-B2022-14.020141<br>Total estimated cost: EUR 8,500,000<br>Total amount of EU budget contribution EUR 8,500,000 | | | |
| **MANAGEMENT AND IMPLEMENTATION** | | | | |
| **14. Type of financing** | **Indirect management** with the entity(ies) to be selected in accordance with the criteria set out in section 4.3.1 | | | |

Summary of the Action

Cuba has developed since the 1980s a leading biotechnology public industry which holds about 1,200 international patents and supplies 60% of the biomedical equipment and products to uphold its national universal health care and to export to third countries. The existing product portfolio is broad, going from treatments against diabetes to meningococcal vaccines. Moreover, in response to the COVID-19 pandemic, Cuba has developed five vaccines candidates based on the viral protein antigens, four of which have been already approved by its national regulatory agency. The scientific and industrial potential of these advancements is plausible, yet meeting global standards remains a bottleneck.

Promoting industry, innovation and infrastructure as well as achieving good health and well-being are part of the Sustainable Development Goals (9, 3). Ensuring efficient epidemiological surveillance also enables the country to effectively address health priorities and emergencies caused by endemic, emerging and re-emerging diseases.

The objective of the action is to strengthen capacities for the development, production, approval and control of relevant, safe and effective biotechnological products, such as vaccines, diagnostics and therapeutic products for more prevalent diseases in the population.

The action will support the training of professionals from participating organizations (including Universities and SMEs) in the biotechnological sector in order to increase capacities for innovation, international collaboration, publications in international scientific journals and project management. It will also help explore opportunities of collaboration within the European Union programmes, including the Horizon Europe Framework Programme for Research and Innovation.

Additionally, the action will allow for the completion of the capacities of the National Control Laboratory and Regulatory Office (CECMED) and its information and communications infrastructure, as well as enhance the development of its human resources through technical scientific exchange with its peers of European regulatory agencies. Furthermore, the action will contribute to the completion of the infrastructure and equipment of the Research and Development Unit of the CIGB-Mariel Biotech Industrial Complex.

As a result, capacities for research, development and regulation of biotechnological products will be strengthened to contribute to the national, regional and global response to health emergencies such as COVID-19 and other health challenges.

Support to technology transfer will additionally contribute to enhance current efforts to adopt a digitalization strategy for the country´s health system (WHO´s *Global strategy on digital health 2020-2025*), based on a high level of data protection and privacy respecting the high international standards established, for example, by the General Data Protection Regulation (GDPR) of the European Union.

# 2 RATIONALE

## 2.1 Context

Cuba has developed since the 1980s a leading biotechnology public industry (BioCubaFarma[1]) which holds about 1,200 international patents and supplies 60% of the biomedical equipment and products to uphold its national universal health care and to export to more than 50 countries. The existing product portfolio is broad, going from treatments against diabetes to meningococcal vaccines. Moreover, in response to the COVID-19 pandemic Cuba has researched and developed five vaccines candidates based on the viral protein antigens, four of which have already been approved by its national regulatory agency.

The development of the country's biotechnological sector would not be possible without the capacity and expertise of the human resources associated with them and including the Cuban academic sector. Women make up 71% of the work force in the sector, as they are the majority of medical university and technological school graduates.[2] Universities in interaction with BioCubaFarma, centres participate in joint research projects for the development and co-development of new biotechnological products. These actions are linked both to joint university-enterprise laboratories (with the potential of the new framework for SMEs) and to the training of the professionals involved, thus making it possible to increase the aggregate value of various products from this industry. Similarly, technical cooperation between countries, scientific, academic and peer-to-peer exchanges play a key role in achieving the proposed objectives. On the other hand, the country lacks the tools for analysing large amounts of data. It is therefore necessary to develop information and communications infrastructures, including an epidemiological intelligence system, in order to respond to the new challenges of a digitalised world while developing advanced methods for data collection, processing and analysis that enable them to acquire knowledge for decision-making, including a regulatory framework for data protection in accordance with international standards.

[1] BIOCUBAFARMA, the Group of Biotechnology and Pharmaceutical Industries of Cuba is a company that research, develop, manufacture and commercialize biopharmaceuticals for prevention, diagnostic and treatment of infectious diseases, cardiovascular diseases, neurodegenerative diseases, autoimmune diseases and cancer, medical equipment, medical devices and other products for Cuban National Healthcare System as well as products for agricultural biotechnology and veterinary medicines. BIOCUBAFARMA gather 32 enterprises in Cuba, 9 of them are commercial companies with import / export capabilities. It has 12 companies, 1 subsidiary company and 2 representation offices outside Cuba. Six (6) companies are joint venture companies (3 in China, 1 in Thailand, 1 in Singapore and 1 in Spain) and the other 6 are 100% wholly-owned companies by BIOCUBAFARMA (1 in Brazil, 1 in Ecuador, 2 in Mexico, 1 in Spain, and 1 in Venezuela).

[2] https://revista.drclas.harvard.edu/cuban-working-women-during-the-pandemic/

This action will help to meet global quality standards and regulatory requirements to ensure quality, safety and efficacy of biotechnological products; leverage alliances with EU companies and financing towards scaled up production; boost research, technology transfer and innovation.

The action is in line with the EU's gender priorities and in particular with the Gender Action Plan III (2021-2025) regarding its thematic area of engagement "Promoting economic and social rights and empowering girls and women".

## 2.2 Problem analysis

In Cuba, despite the achievements in the fields of biotechnology, there are elements that require further progress, such as the development of international scientific cooperation and the increase of R&D capacities, production and regulation of medicines and vaccines, as well as the modernisation of information and communications infrastructure.

The Research and Development Unit of the Biotech Industrial Complex CIGB-Mariel was set up with the aim of expanding the production capacities of the Centre for Genetic Engineering and Biotechnology (CIGB) designed for the production of pharmaceutical ingredients. The infrastructure related to premises, climate system, critical systems, electricity and the rest of the ancillary services are installed and ready to start operation. However, at this point in time, the equipment infrastructure is in an incomplete state hence the opportunity of this project to complete the missing elements which will enable to start producing the various products ready to start clinical studies. The basic missing equipment consist of fermenters, tanks, units of Limlete in Situ, Homogenizers, tubular centralists, tangential filtration equipment, low-pressure chromatography units, freezers, laboratory equipment for processing control, different formulation lines for filling final products or drugs (bulbs, suppositories, and small lyophiser, among others).

CECMED has an international recognition that places it on the WHO Transition List of the new Regulatory Systems Assessment Process and has until 2027 (5 years) to pass the evaluation process to become a WHO listed Authority, the highest international recognition in this area. To achieve this objective, work is carried out on the basis of established assessment indicators, identifying as priorities the completion of the analytical capacities of the National Control Laboratory for pre-qualification by WHO, the strengthening of its communications infrastructure and the development of its human resources as preparation for the assessment process through scientific and technical exchange with its peers and the strengthening of the regulatory dialogue between international actors such as EMA and other agencies, allowing confidence building to facilitate regulatory approval of priority medical products, especially those intended to respond to health emergencies, such as COVID-19.

Moreover, although Cuba has experience in carrying out research and development projects, there is insufficient staff trained to manage and implement them and disseminate them through international impact journals. The University of Havana as a training centre has the capacity to develop training programmes on these topics with links with national and international experts. Therefore, in order to increase these capabilities, it is essential to have a technological infrastructure to facilitate the training of professionals and exchange with experts. Capacity building requires parallel actions in the training of professionals who are part of the entities involved in the project. In addition, training is required for the use of the new technologies installed and computing resources, as well as for the development of new analytical methodologies and the use of assessment tools.

Cuba has a track record of highly successful prevention measures against infectious diseases and the implementation of research and production of competitive biotechnology at international level. The articulation of Cuban and European Union institutions and SMEs with a strong public health and research programme could benefit the people of both regions in urgent matters of global health and pandemic prevention. This will specifically include disease surveillance, ecosystem health and treatment research. This requires the development of an epidemiological intelligence system to monitor the health situation, risks, endemic and emerging diseases and thus inform relevant strategies in prevention, alert status, treatment and response to future health challenges.

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

CIGB-Mariel Biotech Industrial Complex: it is a productive entity that has been designed and built to further develop Cuban biotechnological sector. It has production facilities based on active principles, formulation and filling, product packaging and production support areas. It also has a Research and Development Unit to carry

out the productions that will be used for clinical testing studies. The project will ensure the completion of the infrastructure and equipment of this complex for research and development operations to meet the demand for medicines and novel products from the Health System, in line with environmental practices in terms of preserving natural resources and preventing pollution. This industrial infrastructure will make it possible to develop the products to be used for clinical testing studies.

CECMED-Centre for State Control of Medicines, Equipment and Medical Devices: it is the National Regulatory Authority (NRA), subordinated to the Ministry of Public Health, designated by the Cuban State to regulate and control medicinal products and medical devices for human use subject to health surveillance. It has the task of promoting and protecting the health of the population through an effective and transparent health regulation, control and surveillance system, ensuring medicines, medical equipment and devices, services and other health products with safety, effectiveness and quality. Through this project, the infrastructure of the CECMED National Control Laboratory will be completed, the information and communications infrastructure will be upgraded and the development of technical exchange between regulatory agencies will be promoted with a view to preparing for the WHO regulatory systems assessment process.

University of Havana: it is attached to the Ministry of Higher Education and hosts 400 research projects, 71 international projects including 3 Horizon 2020 projects. It has an excellent talent with teaching, scientific and innovative skills.
Agencies of the Member States: AFD is engaged in lending operations in the sector and planning new operations with shared objectives with the present action, which will be considered for EFSD+ operations.

International and regional organizations (PAHO/WHO/UNDP): these actors will be key to ensuring policy coherence with international standards, timely delivery of equipment and effective transfer of knowledge.

Private sector companies in the European Union: potential participants in joint ventures.

Cuban SMEs: the participation of Cuban SMEs in this project will be encouraged, seeking synergies with the action under the EU-Cuba MIP 2021-2027 to support new economic actors.

Other actors included in this action are the Ministry of Higher Education (MES), with its network of universities, the Ministry of Foreign Trade and Investment (MINCEX), BioCubaFarma, the Ministry of Public Health (MINSAP) and centres such as *Instituto Pedro Kouri*[3], and the Institute for Hygiene and Epidemiology (INHEM).

In addition, this action will be developed in synergy with the ongoing EU programmes in Cuba supporting the biotechnology and health sector, in particular with the LAIF programme supporting MINSAP and the network of SUMA laboratories. As already mentioned, synergy will be ensured with the programmes under the EU-Cuba MIP 2021-2027.

# 3 DESCRIPTION OF THE ACTION

## 3.1 Objectives and expected outputs

The **Overall Objective (Impact)** of this action is to strengthen capacities for the development, production, approval and control of relevant, safe and effective biotechnological products.

The **Specific(s) Objective(s) (Outcomes)** of this action are:

1. To increase research, development, and production of biotechnological products and Active Pharmaceutical Ingredients (APIs), and its potential distribution through multilateral mechanisms such as COVAX.
2. To reinforce the National Regulatory Agency (NRA), *CECMED*, in its regulatory role and in monitoring the safety and efficacy of biotechnological products, according to international standards.
3. To create new opportunities for biotechnological scientific cooperation between EU and Cuba (international scientific project management, public procurement competences, etc).

The **Outputs** to be delivered by this action contributing to the corresponding Specific Objectives (Outcomes) are contributing to:

[3] Institute of Tropical Medicine

Outcome 1 (or **Specific Objective 1**)

1.1 Improved and upgraded R&D Unit capable of researching, developing, producing active pharmaceutical ingredients (IPAs) and operating the characterization laboratory.

1.2 Training of professionals at CIGB Mariel in state of the art production of IPAs and international production and laboratory standards.

Outcome 2 (or **Specific Objective 2**)

2.1 Modernized NRA Control Laboratory with infrastructures, metrology and analytical capacities compatible with international standards for the development, production and control of medicines and biotechnological products.

2.2 Improved capacity of NRA for electronic management of data and business processes.

2.3 Improved capacities of staff of CECMED in the European Union's official standards for the control of medicines, for certification by WHO and for communication.

2.4 Increased capacity of CECMED specialists on international research project management and public procurement.

Outcome 3 (or **Specific Objective 3**)

3.1 Improved capacity of young professionals from Cuba's Biopharmaceutical Industry network, the University of Havana Startups and new SMEs on the biotechnological products for priority diseases and health emergencies.

3.2 Improved capacities of biotechnological industry professionals and NRA for international research project management, with an emphasis on the EU biotechnological sector and related health areas.

3.3 Improved capacities of biotechnological industry professionals, NRA, SMEs and Havana University in scientific writing for publication of relevant Cuban biotechnological research in peer reviewed international journals, with a particular attention for publications of female authors.

3.4. Enhanced capacities in the international publication of the impact of biotechnology research results.

3.5 A proposal developed, in synergy with the LAIF program supporting the health sector and the network of SUMA laboratories to develop of an epidemiological intelligence system.

## 3.2 Indicative activities

Activities related to Specific Objective 1:

1. Purchase of technological equipment for the research and development areas dedicated to the production of active pharmaceutical ingredients (API) for the production of batches for clinical trials at the CIGB Mariel plant. The specification of the equipment shall be adapted to the evolving needs at the time of acquisition.
2. Technological upgrade to strengthen laboratory capacities for physico-chemical and biological characterization of products at the CIGB Mariel plant. The specification of the equipment shall be adapted to the evolving needs at the time of acquisition.
3. Provision and installation of technological infrastructure for the creation and development of a technological classroom linked to face-to-face or virtual integral skills at the Mariel CIGB.
4. Development of workshops and seminars linked to capacity building needs in the industry.
5. Technical assistance according to the needs of the equipment purchased.

Activities related to Specific Objective 2

1. Strengthen actions to ensure the metrological traceability of RNA quality control trials of medicines and vaccines. The specification of the equipment shall be adapted to the evolving needs at the time of acquisition.
2. Technological upgrade of the CECMED National Control Laboratory. The specification of the equipment shall be adapted to the evolving needs at the time of acquisition.
3. Provision and installation of technological infrastructure for the electronic management of the technical and administrative processes of the National Medicines Regulatory Authority.
4. Participation of the NRA in collaborative trials or proficiency tests between Quality Control Laboratories for Medicinal Products.
5. High-level and technical international exchanges for the development of cooperation, preparation and networking activities with a view to certification as a WHO listed Authority.

6. Training for information and communications specialists of the Regulatory Authority and their certification according to internationally required standards, including data protection.
7. Training specialists in the European Union's official standards for the control of medicines and other topics of interest to the project.

Activities related to Specific Objective 3:

1. Develop national professional skills for the management of scientific projects with the European Union.
2. Design and development of a university degree for project management.
3. Training for industry professionals and the National Regulatory Authority in ICH Q5 standards.
4. Setting in University of Havana of an observatory for science, technology and innovation aimed at exploring the opportunities offered by the collaborative agencies for the development of biotechnology in Cuba.
5. Creation of a technological classroom for face-to-face or virtual comprehensive skills at the University of Havana.
6. Develop a multidisciplinary analytical team and proposal for an epidemiological intelligence system, including gender stratified analysis, linked to the strengthened capacities of the SUMA laboratory system coordinated by the Pedro Kouri Institute.
7. Strengthening IT capacities of the Pedro Kouri Institute for analyzing big data, geographical, demographic and climate analysis, aimed at monitoring sustainable equity in health, in accordance with the regulatory framework established by international standards, especially regarding the use of personal data.
8. Develop and launch of a digital platform hosted by BioCubaFarma to facilitate alliances and joint initiatives between SMEs in the biotechnology sector between the European Union and Cuba.
9. The commitment of the EU's contribution to the Team Europe Initiative foreseen under this action plan will be complemented by other contributions from Team Europe partners. It is subject to the formal confirmation of each respective partners' meaningful contribution as early as possible. In the event that the TEIs and/or these contributions do not materialise the EU action may continue outside a TEI framework.

## 3.3 Mainstreaming

**ENVIRONMENTAL PROTECTION AND CLIMATE CHANGE**

This action will promote an environmentally friendly logic with the lowest possible environmental impact by supporting environmental standards in the biotechnological sector and by promoting green economy practices from the upstream stages of the production chain to the final product or service. In addition, the promotion of this biotechnological sector is linked to Cuba's commitment to respecting biodiversity, both by supporting research and innovation centres and by developing projects based on the production of natural products.

**GENDER EQUITY AND HUMAN RIGHTS APPROACH:** In its World Science Report 2021, UNESCO ranks Cuba among the top 20 nations in the world with the highest proportion of female researchers (49 % of Cuban scientific staff are women), and stresses that among the top 10 Academies of Sciences (due to the proportion of female members), 6 are from Latin America and the Caribbean: Cuba has 27 %, the Caribbean (26 %), Mexico and Nicaragua (23 %), Peru (20 %) and Uruguay (19 %).

Cuba's strong contribution to gender equality in the fields of science, technology, engineering and mathematics (STEM) is reinforced by gender parity rates at the national level of decision-making (with 51 % of women in senior positions of state and government), although in science this level should be somewhat strengthened, as only 29 % are women in the Cuban Academy of Sciences.

As part of the new "National Advanced Women Programme", the government has announced the imminent opening of a "Gender Science Observatory" to identify problems, establish public policies and promote gender-sensitive education in families, communities and public servants. The present project will contribute to the mentioned national gender equity challenges in the field of science.

The action will apply the working principles of the human rights based approach (HRBA): applying all human rights for all, meaningful and inclusive participation and access to decision-making, non-discrimination and equality, accountability and rule of law for all, and transparency and access to information supported by disaggregated data.

**HUMAN RIGHTS:** This action contributes to the right to health through access to global public goods such as vaccines and bio-products with high health impact and linked to mechanisms as technology transfer and differential pricing policy, as through the COVAX mechanism, with higher access in low-income countries through multilateral or bilateral systems. The action will pay attention to data protection and the right to privacy. It will

ensure that data collection, treatment and analysis (as well as reporting) respect the international standards and that data are treated in an anonymous manner.

**RESILIENCE AND CONFLICT SENSITIVITY:**
The contribution of biomedicine and health regulation goes beyond SDG3 (ensuring people's health and well-being) by finding responses in research to combat infectious diseases, and by promoting responsible consumption and production [SDG12] with pharmacological products of biological origin. It is a sector with verified gender equality [SDG5] in which women play a very important role, not only in the field of research but also in leading productive companies and research lines.
The Sustainable Development Goals require complex and global solutions that make it indispensable to build alliances with other actors in the system [SDG 17]. Public — private cooperation and international vocation have enabled biotechnology for decades to generate a high social, environmental and economic impact.

## 3.4 Risks and lessons learned

| Category | Risk | Likelihood (high/Media/Low) | Impact (high/medium/low) | Mitigating measures |
|---|---|---|---|---|
| Technical | Overlapping responsibilities between line ministries and responsible agencies | M | M | Close monitoring and multilateral cooperation, in particular with the public agencies and institutions concerned.<br>Close monitoring of results and implementation of corrective measures where necessary |
| Technical / Political | Cuba currently does not comply with many international standards of health /pharmaceutical industry, and others not related to health /pharmaceuticals, such as data protection | H | H | Dialogue and cooperation on the objective of complying with international standards |
| Political | US embargo obstructs free access to products, inputs and equipment | H | H | Continued policy dialogue and advocacy of the benefits of innovation and unhindered access to the market.<br>For purchases from Cuba, it is necessary to search for non-US.<br>To negotiate in advance the permit with OFAC (US Treasury Assets Control Office).<br>To use the access advantage of other agencies with existing permission such as UNDP |

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| Environmental | Natural disasters | M | M | Compliance with national regulations for disaster risk reduction |
| Political | Risk of channeling exports of pre-qualified medicines/vaccines through bilateral agreements with political partners, instead of multilateral channels or at unaffordable prices for low-income countries | H | H | Seek Cuba's participation in global health initiatives, with an emphasis on COVAX, especially in pediatric vaccines against COVID for low-income countries and through other joint procurement mechanisms when appropriate |

**Lessons learnt:**

This action integrates the lessons learned from a number of projects supporting the Biomedicine, Health and Education sector in Cuba over the past 5 years by the European Union and its Member States:

- LAIF-MINSAP project, managed by and linked to AFD loan, aimed at strengthening the SUMA laboratory network (EUR 5.6 million);
- 2 EU - PAHO projects helped to mitigate health impact of the COVID-19 emergency in Cuba (by increasing the availability of critical equipment in intensive care units and strengthen the diagnostic, epidemiological surveillance and therapeutic capabilities of national laboratories for COVID-19).
- VLIR project between the University of Ghent, Belgium and CNEURO 2017-2020, extended due to the pandemic until August 2022. Objective: Creation of a Neuro-technology training programme to tackle cognitive ageing for Cuban and foreign students. Results: creation of a Cuban National School of Neuro-technology for cognitive ageing.
- EU project, MPDL, Society of Bioengineering, Cuban Epidemiology Society, CNEURO 2020-2022. Objective: Reduce the expansion of SARS-CoV-2 among the population of Cuba, with an emphasis on health workers as a group most exposed to COVID-19. Results:
- AECID project, MPDL-IC NEURONIC S.L.- CNEURO 2020-2022. Objective: Support research and innovation to improve the medical response to COVID-19 in Cuba.
- Hubert Curie/Carlos J. Finlay Agreement. University of Montpellier-CNEURO. 2021-2022. Objective: Examine possible synergies between the S1R agonists and Amyloids, and therefore investigate a potential S1R activity of Amyloid compounds.
- The European Union's Horizon 2020 Framework Programme for Research and Innovation, coordinated by UNIVERSITA DEGLI STUDI DI PADOVA (UNIPD) (ITALIA) and participating in the CIGB from September 2021 to December 2024. Title: Repetitions in proteins; refinement of functions, annotation and classification of topologies. Objective: addressing the current biggest challenges in the field of tandem protein repetitions (TRP): analyze, compare and improve existing methods of detection of TRP and improve understanding of functional mechanisms and evolution of PTRs. In the end, the knowledge generated in the project will be incorporated into the most relevant international databases for the benefit of the wider scientific community.
- The European Union's Horizon 2020 Framework Programme for Research and Innovation, coordinated by *Universita degli Studi di Roma Tor Vergata* (UNITOV) and participation of the CIGB. Title: Nano peptides and Nano saccharides for advanced and sustainable materials. Objective: Turn creative ideas from research into innovative products and green manufacturing processes.
- Project between *Mosaiques Diagnostiques*, Therapeutics AG, R.F. Germany and the CIGB from February 2022 to December 2023. Title: Identification of stroke biomarkers using capillary electrophoresis coupled to mass spectrometry. Objective: Study the behavior of a group of biomarkers in samples of Cuban patients who were part of the clinical study conducted 'Courage'. In addition, look for whether the phosphorylation phenomenon can be used as a biomarker to predict the disease.
- Project between the French Committee on Alternative Energy and Atomic Energy (CEA), France and the CIGB from October 2021 to October 2023. Title: Pre-clinical evaluation of vaccine formulations for the treatment of chronic hepatitis 8 and SARS-Co V2. Objective: Characterize immunological mechanisms related to in-HeberNasvac immunization, as well as immune response induction in blood, mucous

membranes and liver and consider the safety of administration of these formulations in the non-human primate model.

- Regional triangular programme Adelante 2 between BioCubaFarma and AECID, 2021-2025. Objective: Contribute to the achievement of the 2030 Agenda and to a more inclusive and sustainable development by promoting and using Triangular Cooperation between Cuba, Latin America and the Caribbean and the Member States of the European Union; promoting the transfer and exchange of knowledge and capacity in the areas of development of biotechnology and its applications for public health and food security in the LAC region and strengthening Cuba's dual role as a provider and recipient of technical and triangular cooperation.
- VLIR/UOS BELGICA project with the University of Leuven (KU Leuven). Objective: Transferring technological and expert capacity in organic synthesis to the Cuban academic sector by promoting a national organic synthesis platform for the preparation of human resources for innovation and cooperation with the agricultural and pharmaceutical industry in the development of high added value compounds, contributing to the creation of a knowledge-based industry and the sustainable development of our country
- VLIR/UOS BELGICA project with Hasselt University. VLIR, Belgium. Objective: Develop research, training and training activities for the analysis of large data masses involving teachers, researchers and professionals from higher education institutions and the Cuban health system.
- VLIR/UOS BELGICA project with Ghent University. Objective: Develop research capacities to conduct pre-clinical studies of Cuban bio agents, with the introduction of novel methodologies based on cell models of cell death and inflammation; based on the establishment of a methodological platform and accreditation of a centre for such studies, to generate trusted pre-clinical results throughout the country and to speed up the transfer of new national medicines to the clinic.
- Project. Glacier — German-Latin American Centre for Research and Training in Effects and Epidemiology with German and Latin American institutions Objective: Create a large network of higher education institutions, research institutes, public bodies and biopharmaceutical companies from eight Latin American countries and Germany for research and capacity building in the field of prevention and treatment of infectious diseases.
- BMBF project with University of Ulm Germany. Objective: IDEN Notification of antimicrobial peptides derived from terrestrial, river and marine invertebrates active against micro-organisms of medical importance
- Marie Sklodowska-Curie Actions (MSCA) with Strasbourg University. France (UNISTRA), degli Studi University of Rome Tor Vergata, Italy (UNITOV), Naples TE, Barcelona, Spain (NT), University degli Studi de Parma, Italy (UPR) target**:** Provide scientists with diverse experience in supramolecular chemistry, material chemistry, nucleic acid nanotechnology, molecular biology, biomedicine, etc. The opportunity to develop and implement sensitive hybrid materials for programmable drug delivery applications, focused on cancer therapy

## 3.5 The Intervention Logic

The action will strengthen capacities for the development, production, approval and control of relevant, safe and effective biotechnological products, such as vaccines, therapeutic products against diseases with a high incidence in the population.

If the infrastructure and equipment of the CIGB-Mariel Biotechnology Industrial Complex is completed (with the action contribution), mainly in the areas of research and development for the production of active pharmaceutical ingredients and the manufacture of new products for the production of batches that can be used in clinical trials, this will allow the Cuban Biotechnological industry to further develop. If the standards of the National Control Laboratory (CECMED) and the NRA's information and communications infrastructure are upgraded, and the development of its human resources is enhanced through technical scientific exchange with its peers of European regulatory agencies, Cuban biotechnology industry will gain further access to the international markets.

In addition, if human resources' capacities from for BioCubaFarma, CECMED and the University were to be strengthened in the field of project research management, as well as in international scientific publication production, and the development of an epidemiological intelligence system, the opportunities for Cuban Research community to participate in the short term in European calls for proposals would be maximised. Provision is made for the creation of technology classrooms, and research networks for the development of international Scientific Cooperation Projects with a hands-on approach.

As regards horizontal interventions in the biotechnological environment**,** the action will provide simultaneous support to the Biotech and Pharmaceutical Industries Group, BioCubaFarma and the CIGB-Mariel Biotech Industrial Complex for the development and production of high-quality, safe, effective and affordable biotechnological products.

Based on the above and given the outputs to be delivered, the proposed integrated intervention, combining support to the industry, the regulatory agency and the University will secure the development of human, technical, and quality standards of the Cuban biotechnological sector. The action will hence be able to make a valuable contribution to the country's biotechnological sector by gaining access to the wider international market as well as to its economic and social development achieving a positive impact on the entire Cuban population.

## 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.

| **Results** | **Results Chain:** Main expected results (max. 10) | **Indicators:** (at least one indicator per expected result) | **Baselines** (values and years) | **Targets** (values and years) | **Sources of data** | **Assumptions** |
|---|---|---|---|---|---|---|
| **Impact / Overall Objective** | To strengthen capacities for the development, production, and approval of relevant, safe and effective biotechnological products | Number of new biopharmaceutical products developed jointly with EU partners | TBD in the inception period | TBD in the inception period | NRA – CECMED data | Not applicable |
| **Outcome 1 / Specific Objective 1** | To increase research development, and production of biotechnological products and Active Pharmaceutical Ingredients (APIs), and its potential distribution through multilateral mechanisms such as COVAX | 1.1. Number of products developed, disaggregated by biotechnological products, APIs, other<br>1.2. Number of products certified to be introduced to production<br>1.3. Number of products screened by the CIGB Mariel | 1.1. 0 in 2022<br>1.2. 0 in 2022<br>1.3. 0 in 2022 | 1.1. TBD in the inception phase<br>1.2. TBD in the inception phase<br>1.3. TBD in the inception phase | 1.1. Internal documents on development of the products by CIGB Mariel<br>1.2. Certification received from National Regulator<br>1.3. Protocols and conclusions of screening | CIGB Mariel is supported by the government, international partners and investors to further develop the line of innovative production, and to continuously train and enhance the skills of the personnel |

| Results | Results Chain:<br>Main expected results (max. 10) | Indicators:<br>(at least one indicator per expected result) | Baselines<br>(values and years) | Targets<br>(values and years) | Sources of data | Assumptions |
|---|---|---|---|---|---|---|
| **Outcome 2 /** Specific Objective 2 | To reinforce the National Regulatory Agency (NRA), CECMED, in its regulatory role and in monitoring the safety and efficacy of biotechnological products, according to international standards | 2.1. Status of WHO certification of the National Regulatory Agency (NRA)<br>2.2. Average time needed for screening a biotechnological or a pharmaceutical product, disaggregated by product groups<br>2.3. Status of public communication by the NRA<br>2.4. Number of joint projects with European Agencies / Regulators<br>2.5. Status of digitalisation of internal business processes of NRA | 2.1. None by 2022<br>2.2. TBD in the inception period<br>2.3. None by 2022<br>2.4. TBD<br>2.5. Not digitalised | 2.1. Performance and NRA found compatible with the standards of WHO Global Assessment Tool for Regulatory Authorities by <5 years ><br>2.2. TBD in the inception period<br>2.3. Regular reports issued in <2 years> and communication organised in <2 years><br>2.4. TBD in the inception period<br>2.5. Fully digitalised | 2.1. WHO certification report<br>2.2. Internal NRA reports on specific products<br>2.3. Reports and communications issued<br>2.4. Projects and their approval by the parties<br>2.5. The NRA IT department report | CECMED further receives a dedicated support by the government to develop its systems and capacities, and has an institutional development plan<br><br>WHO and EU Agencies / Regulators support CECMED to plan and organise the certification and launch projects |
| **Outcome 3 /** Specific Objective 3 | To create new opportunities for biotechnological scientific cooperation between EU and Cuba (international scientific project management, public procurement competences, etc.) | 3.1. Number of graduates from the Havana University who graduate from programme on project management<br>3.2. Number of professionals using ICH Q5 guideline and technical facilities created by the Action<br>3.3. Number of publications in peer reviewed international scientific periodicals | 3.1. 0 by 2022<br>3.2. 0 by 2022<br>3.3. 0 by 2022<br>3.4. TBD in the inception period | 3.1. TBD in the inception period<br>3.2. TBD in the inception period<br>3.3. TBD in the inception period<br>3.4. TBD in the inception period | 3.1. Havana University graduates' records<br>3.2. NRA's observations, data from scientific observatory<br>3.3. Publications in the periodicals<br>3.4. Yearly communications | The government, investors and biopharmaceutical industry invests into the further maintenance and development of the established systems, infrastructure and practices of scientific-research development in the country |

| Results | Results Chain: Main expected results (max. 10) | Indicators: (at least one indicator per expected result) | Baselines (values and years) | Targets (values and years) | Sources of data | Assumptions |
|---|---|---|---|---|---|---|
| | | 3.4. Level of availability of epidemiological information both for research and for public awareness. | | | | |
| **Output 1** related to Outcome 1 | 1.1. Improved and upgraded R&D Unit capable of researching, developing, producing active pharmaceutical ingredients (IPAs) and operating the characterization laboratory | 1.1.1 Status of modernisation of R&D Unit of CIGB Mariel | 1.1.1 Not modernized, equipment and technologies are obsolete in 2022 | 1.1.1 Modernized; equipment and technologies are up do date | 1.1.1 Provisional and final certificates of acceptance of modernization and equipment by CIGB Mariel | CIGB Mariel is capable of further maintenance and upgrades and has a respective plan |
| **Output 2** related to Outcome 1 | 1.2. Training of professionals at CIGB Mariel in state of the art production of IPAs and, international production and laboratory standards. | 1.2.1 Status of the technology classroom created at the Mariel CIGB<br><br>1.2.2 Number of CIGB Mariel specialists trained to master the state-of-the-art production of IPAs and laboratory characterisation (** GERF 2.14) | 1.2.1 CIGB Mariel does not have a tech classroom for the training of its specialists<br><br>1.2.2 '0' by 2022. | 1.2.1 CIGB Mariel has a modern and an accomplished tech classroom for training<br><br>1.2.2. TBD in the inception period | 1.2.1 Provisional and final acceptance certificates by CIGB Mariel<br><br>1.2.2 Pre- and post-training tests, sign-in lists | CIGB Mariel has a plan for maintaining and keeping upgraded the tech classroom<br><br>Trained specialists stay at their job |
| **Output 1** related to Outcome 2 | 2.1. Modernized NRA Control Laboratory with infrastructures, metrology and analytical capacities compatible with international standards for the development, production and control of medicines and biotechnological products. | 2.1.1. Status of modernization of NRA Control Laboratories | 2.1.1 None by 2022 | 2.1.1 The infrastructure is modernized, equipped with new equipment, including for metrological and analytical work | 2.1.1 Provisional and final acceptance by the NRA / CECMED | The NRA / CECMED is supported with sufficient budgets and investments to further maintain and develop the Laboratory<br>It has a plan and respective funding for annually decided number of collaborative studies and new analytical methods |
| | | 2.1.2. Status of the Purchased reference materials (RMs) for work MR establishment. | 2.1.2. To be defined in the inception period | 2.1.2. TBD in the inception period | 2.1.2. Reports on the collaborative studies carried out | |

| Results | Results Chain: Main expected results (max. 10) | Indicators: (at least one indicator per expected result) | Baselines (values and years) | Targets (values and years) | Sources of data | Assumptions |
|---|---|---|---|---|---|---|
| | | 2.1.3. Number of new analytical methodologies per year with the support of the Action. | 2.1.3. To be defined in the inception period | 2.1.3. To be defined in the inception period | 2.1.3. NRA's / project's reports on the analytical methodologies implemented | |
| **Output 2** related to Outcome 2 | 2.2. Improved capacity of NRA for electronic management of data and business processes | 2.2.1. Status of software at RNA Laboratory for data management<br>2.2.2. Status of the gender and human rights sensitive guidelines on data processing and protection, in line with international standards. | 2,2,1, Not installed by 2022<br><br>2.2.2. None by 2022 | 2.2.1. Installed, tested / staff trained on how to use by *TBD in the inception period*<br>2.2.2. Drafted, agreed, implemented and monitored by *TBD in the inception period* | 2.2.1. Software installed, tested, staff trained on and operates it<br>2.2.2. Project's monitoring reports, NRA's IT Department's reports | NRA has incorporated the upgrades and continuous staff training in its institutional plan and budgets |
| **Output 3** related to Outcome 2 | 2.3. Improved capacities of CECMED staff on the European Union's standards for the control of medicines manufacturing, for certification by WHO and for communication. | 2.3.1. Number of NRA specialists participating in capacity building events to comprehend and prepare for WTO certification – Global Assessment Tool for Regulatory Authorities, disaggregated by sex (** GERF 2.14) | 2.3.1. 0 by 2022 | 2.3.1. TBD in the inception phase | 2.3.1. Sign-in lists | Personnel trained and participated in the capacity building events stay at their job |
| | | 2.3.2. Number of personnel of NRA participating in face-to-face meetings with counterpart NRAs per year defined by WHO core functions and modules, disaggregated by sex(** GERF 2.14) | 2.3.2. 0 by 2022 | 2.3.2. TBD in the inception phase | 2.3.2. Sign in lists | |

| Results | Results Chain: Main expected results (max. 10) | Indicators: (at least one indicator per expected result) | Baselines (values and years) | Targets (values and years) | Sources of data | Assumptions |
|---|---|---|---|---|---|---|
| | | 2.3.3. Number of NRA personnel learning on EU's official standards on medicines control, disaggregated by sex (** GERF 2.14) | 2.3.3. 0 by 2022 | 2.3.3. TBD in the inception period | 2.3.3. Pre- and post-training tests, sign-in lists | |
| | | 2.3.4. Number of NRA personnel capable of designing communication strategy, campaigns and carrying those out, disaggregated by sex (** GERF 2.14) | 2.3.4. 0 by 2022 | 2.3.4. TBD in the inception period | 2.3.4. Pre- and post-training tests, sign-in lists | |
| **Output 4** related to Outcome 2 | 2.4. Increased capacity of CECMED specialists on international research project management and public procurement | 2.4.1. Number of NRA personnel trained on project management, disaggregated by sex (** GERF 2.14) | 2.4.1. 0 by 2022 | 2.4.1. TBD in the inception period | 2.4.1. Pre- and post-training tests, sign-in lists | |
| **Output 1** related to Outcome 3 | 3.1. Improved capacity of young professionals from Cuba´s Biopharmaceutical Industry network, the University of Havana Start-ups and new SMEs on the biotechnological products for priority diseases and health emergencies | 3.1.1. Status of a Design of a graduate programme for biopharmaceutical scientific projects' management | 3.1.1. Not designed by 2022 | 3.1.1.. Designed, agreed, and tested at Havana University by <4 years> | 3.1.1. The programme and the minutes of discussion, conclusion of the faculty<br>— Courses provided | The study programme is officially approved and incorporated into the curricula of the Havana University |
| **Output 2** related to Outcome 3 | 3.2. Improved capacities of biotechnological industry professionals and NRA for international research project management, with an emphasis | 3.2.1. Number of professionals trained to comprehend and use the ICH Q5 guidelines, disaggregated by institution and sex (** GERF 2.14) | 3.2.1. 0 | 3.2.1. To be defined in the inception period | 3.2.1. Pre- and post-training tests, sign-in lists | The trained professionals stay at their job |

| Results | Results Chain: Main expected results (max. 10) | Indicators: (at least one indicator per expected result) | Baselines (values and years) | Targets (values and years) | Sources of data | Assumptions |
|---|---|---|---|---|---|---|
| | on the EU biotechnology sector and related health areas | | | | | |
| **Output 3** related to Outcome 3 | Improved capacities of biological industry professionals, NRA, SMEs and Havana University in scientific writing for publication of relevant Cuban biotechnological research in peer reviewed international journals, with a particular attention for publications of female authors | 3.3.1. The status of the scientific observatory for science and innovation (STI). | 3.3.1. No STI observatory by 2022 | 3.3.1. STI observatory is set-up at Havana University | 3.3.1. Minutes of discussion on the completion of the observatory; Website of the observatory<br>— Number of visits. | The created facilities, including observatory, tech classroom, digital platform are properly accepted, used and maintained by the host institutions. |
| | | 3.3.2. Status of the technology classroom at the University of Havana | 3.3.2. None by 2022 | 3.3.2. Established and operational by <specify time> | 3.3.2. Acceptance certificate by the Havana University | |
| | | 3.3.3. Status of the digital platform for alliances and partnership agreements between SMEs in the European Union and Cuba, in synergy with the Trade and Investment Points of Single Contact. | 3.3.3. There is no specific digital platform for the biotechnology sector by 2022. | 3.3.3. The digital platform is established at <specify the host institution> by <specify time> | 3.3.3. The platform and its acceptance by the host institution or the operator . | |
| **Output 4** related to Outcome 3 | 3.4. Enhanced capacities in the international publication of the impact of biotechnology research results. | 3.4.1. Number of professionals trained master scientific writing, disaggregated by institution and sex (** GERF 2.14)<br>. | 3.4.1. 0 by 2022 | 3.4.1. TBD in the inception phase | 3.4.1. Pre- and post-training tests, sign-in lists | The professionals continue their research and publish articles. |
| **Output 5** related to Outcome 3 | 3.5. A proposal developed, in synergy with the LAIF program supporting the health sector and the network of SUMA laboratories to develop of an epidemiological intelligence system. | 3.5.1. Status of the multidisciplinary analytical team<br><br>3.5.2. Status of the proposal for an epidemiological intelligence system of the SUMA laboratory system | 3.5.1. None by 2022<br><br>3.5.2. None by 2022 | 3.5.1. Established by <specify time><br><br>3.5.2. Done and agreed with LAIF Secretariat | 3.5.1. The declaration by the participants, list and the first meeting minutes<br><br>3.5.2. The proposal and its discussion / appraisal at LAIF | The team and the proposal are efficiently utilised to launch the LAIF intervention.<br><br>The team is further motivated and used to strengthen the national epidemiological system. |

| Results | Results Chain: Main expected results (max. 10) | Indicators: (at least one indicator per expected result) | Baselines (values and years) | Targets (values and years) | Sources of data | Assumptions |
|---|---|---|---|---|---|---|
| | | coordinated by the Pedro Kouri Institute. | | | | |
| | | 3.5.3. Status of IT capacities for processing and analysing big data, geographical, demographic and climate analysis | 3.5.3 Very limited. | 3.5.3 Number of professionals trained to perform big data analysis, disaggregated by institution and sex. | 3.5.3 Assessment of IT capacities acquired by the end of the programme. | The team has enhanced IT capacities to strengthen the national epidemiological system. |

# 4 IMPLEMENTATION ARRANGEMENTS

## 4.1 Financing Agreement

In order to implement this action, it is envisaged to conclude a Financing Agreement with Cuba

## 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 50 months from the date of entry into force of the financing agreement
Extensions of the implementation period may be agreed by the Commission's responsible authorising officer by amending this Financing Decision and the relevant contracts and agreements.

## 4.3 Implementation Modalities

The Commission will ensure that the EU appropriate rules and procedures for providing financing to third parties are respected, including review procedures, where appropriate, and compliance of the action with EU restrictive measures[4].

### 4.3.1 Indirect Management with a pillar assessed entity

This action may be implemented in indirect management with a pillar assessed entity, to be selected by the Commission services using the following criteria:
(a) Experience in project management in the areas of action;
(b) Experience in capacity building of actors in the field of biotechnology, regulation of medicinal products, scientific cooperation and epidemiological intelligence;
(c) Experience with equipment import processes in the project areas.

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

With reference to point 4.3.1 in the event of exceptional circumstances beyond the Commission's control, direct management (procurement) will be considered according to the criteria defined in section 4.3.1 in support of the objectives of this action.

### 4.3.3 Scope of geographical eligibility for procurement and grants

Geographical eligibility in terms of the place of establishment for participation in procurement and grant award procedures and the origin of supplies purchased, as set out in the basic act and set out in the relevant contractual documents, shall apply.

The Commission's authorizing officer responsible may extend geographical eligibility for reasons of urgency or unavailability of services in the markets of the countries or territories concerned, or in other duly justified cases where the application of the eligibility rules would make it impossible or excessively difficult to carry out this action (Article 28(10) of the NDICI-Global Europe Regulation).

[4] 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 Indicative budget

| Indicative Budget Components | EU contribution (amount in EUR) |
|---|---|
| **Implementation modalities – cf. section 4.3** | |
| **SO1: To increase research, development, and production of biotechnological products and Active Pharmaceutical Ingredients (APIs), and its potential distribution through multilateral mechanisms such as COVAX**<br>(Indirect Management) | 6,025,000 |
| **SO2: To reinforce the National Regulatory Agency (NRA), *CECMED*, in its regulatory role and in monitoring the safety and efficacy of biotechnological products, according to international standards**<br>(Indirect Management) | 1,975,000 |
| **SO3: To create new opportunities for biotechnological scientific cooperation between EU and Cuba (international scientific project management, public procurement competences, etc)**<br>(Indirect Management) | 500,000 |
| **Evaluation** — see section 5.2<br>**Audit** — see section 5.3 | Covered by another Decision |
| **Totals** | 8,500,000 |

## 4.5 Organizational Set-up and Responsibilities

A Steering Committee will provide strategic guidance and review overall implementation. It will be chaired by BioCubaFarma and composed of MINSAP, MES, MINCEX, the participating research centres and the European Union Delegation to Cuba. It will convene at least three times a year to ensure overall coordination of the Action, discuss the strategic approach for the next four months, share best practices and, if necessary, suggest amendments based on lessons learned from previous projects.
As part of its prerogative in budget implementation and to safeguard the financial interests of the Union, the Commission may participate in the above governance structures set up for oversee the implementation of the action.

## 4.6 Pre-conditions

The financing agreement for this action will be signed with MINCEX and the European Union prior to the signature of the contract and the start of activities.

# 5 MEASUREMENT OF IMPLEMENTATION

## 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 end, the implementing partner shall establish a permanent internal, technical and financial monitoring system for the action and produce regular progress reports (not less than annually) and final reports. Each report shall provide an accurate account of how the action is being implemented, difficulties encountered, changes introduced, and the results achieved (outputs and direct outcomes); these shall be measured by corresponding indicators, using as a reference either the Logframe matrix (for project modality) or the partner's strategy, policy or reform action plan list (for budget support).

Reports shall be laid out in a way that allows monitoring of the work plan, its execution and of the budget details for the action. The final report will cover all aspects of the action and the entire period of implementation.

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

Roles and responsibilities for data collection, analysis and monitoring: the specific monitoring and reporting measures will be designed with the implementing partners and will be consistent with the logical framework matrix of this Action Document.

## 5.2 Evaluation

Having regard to the importance of the action, mid-term and final evaluation will be carried out for this action via independent consultants contracted by the Commission.

The mid-term evaluation will be carried out for problem solving and learning purposes, in particular with respect to the possibility to launch a second phase of the action

The final or ex-post evaluation 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 has contributed to EU innovation strategy and reinforced research cooperation.

Appropriate expertise on gender equality and HRBA will be ensured in monitoring and evaluation teams

The Commission shall inform the implementing partner at least 2 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.

Evaluation reports may be shared with partners and other key stakeholders following best practices for the dissemination of evaluations. The implementing partner and the Commission shall analyze the findings and recommendations of the evaluations and, where appropriate, make the necessary adjustments.

The financing of the evaluation shall 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.

Special surveillance missions by the Commission shall be carried out as necessary, subject to an acceptable prior warning. The evaluation will be made on the basis of the indicators, as set out in the logical framework (see section 3.5) of the expected results. Process indicators will also be used to measure the progress of implementation.

# 6 STRATEGIC COMMUNICATION AND PUBLIC DIPLOMACY

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

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

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

**Appendix 1 REPORTING IN OPSYS**

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

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

The present Action identifies as;

| **Action level** | | |
|---|---|---|
| ☒ | Single action | Present action: all contracts in the present action |