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ANNEX 1

to the Commission Implementing Decision on the financing of the annual action plan part 1 in favour of the Americas and the Caribbean for 2023

Action Document for Strengthening the Mexico's Regulatory System of Medicines and Vaccines (EU4Health)

ACTION PLAN 2023

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

1 SYNOPSIS

1.1 Action Summary Table

1. Title **OPSYS business reference** **Basic Act**	**Strengthening the Mexico's Regulatory System of Medicines and Vaccines (EU4Health)** OPSYS number NDICI LA/2022/61859 Financed under the Neighbourhood, Development and International Cooperation Instrument (NDICI-Global Europe)/ Overseas Association Decision/European Instrument for International Nuclear Safety Cooperation Regulation
2. Team Europe Initiative	No This is a strategic Initiative on health in Mexico
3. Zone benefiting from the action	Mexico and Central America
4. Programming document	The Americas and the Caribbean Regional Multiannual Indicative Programme 2021-2027
5. Link with relevant MIP(s) objectives / expected results	**Priority area 5: Social cohesion and addressing inequalities** **Specific objective 3: Strengthening systems to protect people from risks and ensure equal access to public goods and services (particularly for 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 **R2)** Social protection systems are adequate, reinforced and shock-resilient, and reach the most vulnerable.
PRIORITY AREAS AND SECTOR INFORMATION	
6. Priority Area(s), sectors	Support to the EU – Mexico Global Agreement, Health

7. Sustainable Development Goals (SDGs)	Main SDG (1 only): SDG 3: Good Health and Well-being Other significant SDGs : - SDG 4: Quality Education - SDG 10: Reduced Inequalities -SDG 17: Strengthen the means of implementation and revitalise the global partnership for sustainable development			
8 a) DAC code(s)	12000-HEALTH			
8 b) Main Delivery Channel	*European Commission - Development Share of Budget - 42001*			
9. Targets	☐ Migration ☐ Climate ☐ Social inclusion and Human Development ☐Gender ☐ Biodiversity ☐ Education ☐ Human Rights, Democracy and Governance			
10. Markers **(from DAC form)**	**General policy objective** @	**Not targeted**	**Significant objective**	**Principal objective**
	Participation development/good governance	☐	■	☐
	Aid to environment @	■	☐	☐
	Gender equality and women's and girl's empowerment	☐	■	☐
	Trade development	☐	■	☐
	Reproductive, maternal, new-born and child health	■	☐	☐
	Disaster Risk Reduction @	■	☐	☐
	Inclusion of persons with Disabilities @	☐	☐	☐
	Nutrition @	■		☐
	RIO Convention markers	**Not targeted**	**Significant objective**	**Principal objective**
	Biological diversity @	■	☐	☐
	Combat desertification @	■	☐	☐
	Climate change mitigation @	■	☐	☐
	Climate change adaptation @	■	☐	☐
11. Internal markers and Tags:	**Policy objectives**	**Not targeted**	**Significant objective**	**Principal objective**
	Digitalisation @	☐	■	☐

	digital connectivity digital governance digital entrepreneurship digital skills/literacy digital services	YES ☐ ■ ☐ ■ ■	NO ■ ☐	
	Connectivity @	☐	■	☐
	digital connectivity energy transport health education and research	YES ☐ ☐ ■ ■	NO ■ ■ ☐ ☐	
	Migration @ (methodology for tagging under development)	■	☐	☐
	Reduction of Inequalities @ (methodology for marker and tagging under development)	■	☐	☐
	Covid-19	☐	■	☐
BUDGET INFORMATION				
12. Amounts concerned	Budget line(s) (article, item): BGUE-B2023-14.020140-C1-INTPA Total estimated cost: EUR 1 500 000 Total amount of EU budget contribution EUR 1 500 000 This Action is part of the EU Global Health Strategy and is linked and will complement the EU-LAC partnership on vaccine production and health systems resilience, including political support and engage in exchange of good practices from the European Union Member States such as Denmark, Germany, Hungary, Italy, Spain, and The Netherlands, which have already manifested their interest (this list may be further completed). This intervention paves the way for a possible future Team Europe Initiative on Health in Mexico. Synergies between the EU and EU Member States (MS) initiatives contributing to this partnership will be systematically sought. EU MS participation in key events will be encouraged to promote the global values championed by the EU in Mexico and foster coordination of overall health security, resilience and regulation.			
13. Type of financing	**Indirect management** with the entity to be selected in accordance with the criteria set out in section 4			

1.2 Summary of the Action

COVID-19 has strongly impacted people, communities and societies, generating a drastic reduction of economic and social activities worldwide. Research suggests that the recession generated by the COVID-19 pandemic is the deepest since the end of World War II, and it's the first time since 1870 that so many economies worldwide have experienced a decline in per capita output.

With 11 108 486 cases including 383 895 deaths reported across Central America and Mexico as of 25 October 2022, the COVID-19 pandemic has highlighted the weaknesses in the region's health systems and its capacity to effectively prevent and control such health shocks and challenges. Mexico has reached more than 7 million cases, and more than 330 000 deaths since the beginning of the pandemic to October 2022.

Beyond immediate response and the prospect of potential decisive improvements through COVID-19 vaccination, structural challenges were made evident by the infection outbreak and still persist in Mexico and the region in terms of shortcomings in health preparedness and response capacities against other threats beyond communicable diseases, as well as gaps in medicine quality, harmonisation and regulation as well as health financing. In particular, the public health system of Mexico remains challenged by structural fragmentation, limited domestic resourcing, fragmented manufacturing capacity, questionable procurement practices, as well as limited cross-national harmonisation and coordination, and low health and social financing. Mexico public spending for health represents only the 5.5% of the GDP, one of the lowest of the OECD countries. Social assistance for the most vulnerable groups, managed through cash-transfer temporary presidential programmes, has slightly improved the life conditions of part of the poorest population over the past year, but inequalities remain important and access to social services limited. Moreover, taxes and transfers have limited distributional potential reducing Mexico's Gini coefficient (00.51) by only 2 percentage points (OECD, 2022). The COVID-19 pandemic crisis has also revealed the dependence of the region on raw material, medicine and other health technologies from abroad, the vulnerability of global supply chains and the heterogeneity in terms of health technologies research, development and production capacity in Central America. ECLAC estimates that in 2018 only 4% of Latin American and Caribbean imports of a strategic group of health technologies came from the sub - region itself. Furthermore, research and development of new technologies remain limited and underfinanced. These structural challenges adversely affect the resilience and capacity of the health systems to address the current pandemic and future health crisis, and the path towards sustainable and equitable development and growth.

Inequality remains high, negatively affecting economic growth, undermining social cohesion, and fuelling political instability and population's displacement. In this context, the COVID-19 crisis has further exacerbated the conditions of the most vulnerable groups, because of their lack of access to healthcare, their level of unpaid work, and the level of violence existing in that spaces, weather public or private. Women in particular are disproportionally exposed since they are in the frontline and offer performing several tasks at the same time. Actions can be undertaken to reduce inequalities, notably in the area of socio-economic development and access to decent services for All.

The European Union (EU) –Latin America and the Caribbean (LAC) partnership on health resilience and vaccine production, proposed in June 2022 by Commission President Ursula von der Leyen with the support of the Prime Minister of Spain Pedro Sanchez, is the response to the high interest manifested by LAC leaders in underpinning their health systems and boosting local manufacturing capacities. The partnership, which is to be considered as contribution to the EU Global Health Strategy, intends to sustain ongoing regional efforts, notably the Plan for self-sufficiency in health matters, endorsed by the Community of Latin American and Caribbean States) in September 2021, which sets out lines of action to strengthen capacities to produce and distribute vaccines and medicines in the region. As discussed at the EU-LAC leaders meeting in December 2021, diversification of global pharmaceutical production is essential for global health security and the EU is keen to contribute to the LAC success of pharmaceutical, biotech and med-tech industries in an ecosystem conducive to ensuring equitable access to quality products.

Against this background, the Action presented in the current document intends to help strengthening capacities to produce and distribute high quality vaccines and medicines in Mexico and in the sub-region of Central America to ensure the diversification of global pharmaceutical production, improve global health security, the access for quality medicine for all and promote the success of pharmaceutical, biotech and med-tech LAC based industries. This approach supports the ECLAC engagement to enhance sanitary self-sufficiency and promote cross-national health emergency coordination in preparing for and responding to future health crises and challenges, based on the lessons learnt from COVID-19.

The areas of interventions of this specific Action are relating to sanitary regulatory frameworks in Mexico, with positive spill overs in Central America. The Action will support capacity building of the Federal Commission for the Protection against Sanitary Risks in Mexico (Comisión Federal para la Protección contra Riesgos Sanitarios - Cofepris) to strengthen its regulatory mandate, update its Global Benchmarking Tools (GBT) in order to upscale its ranking in the list of WHO Listed Authorities framework – WLA, and play a pivotal role at sub –regional level and for cross-national coordination for health regulation, harmonisation, security, and resilience. This will also include the strengthening of regulatory system governance and stewardship, and encourage regulatory systems to contribute to the development and manufacture of health technologies, promoting an environment of predictability and regulatory oversight for locally manufactured products. This will, in turn, allow Mexico and the sub - region to reinforce and maintain their all-hazard preparedness and response capacities, in particular with reference to medicine and other health technologies regulation and harmonisation and guarantee quality-assured, effective, and safe vaccines, medicines and medical devices. The EU will also support, through its regional partnership on health resilience and vaccine production, the ECLAC sanitary plan aiming at improving resilience, security surveillance and coordination of LAC answer to health challenges and emergency crisis.

Through a bilateral approach, benefiting mainly Mexico involving also Central America and EU countries, the Action will be implemented by the *Pan American Health Organization* (PAHO) office in Mexico, in close coordination with the European Commission, Cofepris, the Central America regulatory bodies and the Regulatory Agencies of the EU Member States participating in the project as well as in line with the PAHO office in Washington. In particular the project will complement and integrate the regional initiative on health that is under formulation and will be implemented by PAHO Washington. The choice of PAHO is based on its global leadership on health issues and its country experience in Mexico, including its ongoing initiatives to support medical regulation and harmonisation such as for example the PAHO's Collaborative Registration Process and the Pan American network of harmonization of medicine regulation (Red Panamericana de Armonizacion de la Reglamentacion Farmaceutica – PARF). On top of its focus on regulatory framework and regional harmonisation, the Action will also offer the opportunity to undertake high level and technical dialogues on areas of interest between the EU, EU Member States and Mexico competent authorities for medicine regulation and strengthen relations and links.

From an EU perspective, this Action is fully in line with the EU Global Health Strategy (2022), aimed at improving global health security and delivering better health for all in a changing world. In particular in its commitment to fight inequalities in global health and in combatting health threats in the age of pandemics, the EU reasserts its responsibility for tackling key global challenges and health globally, which is fully in line with the spirit, the vision and the practical interventions of this Action. The project itself represents an opportunity to contribute to global public health goals in Central America, stimulate growth and decent jobs, bring in private sector innovation, facilitate trade, diversify global value chains, and reinforce scientific, diplomatic and human bonds between Europe and Latin America. Furthermore, it intends to help strengthening the local capacities to produce, distribute and facilitate the access to high quality vaccines and medicines to ensure the diversification of pharmaceutical production, improving global health security, and the access to quality medicine for all and promoting pharmaceutical, biotech and med-tech LAC based industries through a reinforced medicine regulatory framework, enhanced system efficiency and partnership with relevant actors, notably from the EU. It aligns with the Global Gateway Strategy in its goal to strengthen supply chains and local vaccines production as well and with the Agenda 2023, in particular when it refers to the promotion of health for all.

The Action will complement the activities conducted at regional level by PAHO Washington over the same timeframe, including the ones that will be carried out by PAHO in the framework of the EU TEI to support the LAC sanitary plan, as well as the activities address pandemics and health related issues that will be carried over by the EU-Mexican Joint Fund.. Indirectly the Action will also contribute to the EU-Mexico dialogue on human right international standards and principles. By addressing vulnerability and inequality in the health sector, the Action will have an important impact on social justice, and by improving citizens' health, on productivity and therefore on economic and social development in the country and the region.

2 RATIONALE

2.1 Context

With a population of 129 million of inhabitants, Mexico is the 15th largest global economy, the second largest in Latin America. Mexico has been one of most affected countries worldwide with regard to the pandemic. According to official statistics, which most probably do not reflect the reality on the ground, the number of COVID-19 infections has surpassed 7 million in 2022 while the official death-toll was over 330,000 - based on excess in mortality, the real figure could amount to over 600,000 victims. The country has the fifth highest number of total deaths after the United States, Brazil, India and Russia and has had throughout the pandemic one of the lowest per-capita COVID-19 testing rates in the world. At regional level, the COVID-19 infection in Central America has surpassed 4 million in 2022 while the official death toll was over 53,000. Vulnerability and fragility have also drastically increased during the pandemic in the whole region, mostly for the most disadvantaged groups.

In addition to its immediate human impact, the pandemic has had a disruptive effect on the economies of the region and on people's lives. The weaknesses of the region's health systems have made these partners and their population susceptible to health and economic shocks caused by outbreaks and other health emergencies and the ensuing economic downturn, and has risen the commitment of these countries to more coordinated and harmonised health institutions and agencies. For example in Mexico, with an informal sector reaching over 60% of the active population, in two years the pandemic added 16 million more people to extreme poverty. The sanitary crisis also revealed the fragility and fragmentation of the national healthcare sector (between 2018 and 2020, the part of the Mexican population living in poverty and extreme poverty increased from 41.9% to 43.9% and 7% to 8.5%, respectively).

International evaluations of the Mexican and regional preparedness and response capacities against health emergencies have pointed out various weaknesses in the field of health security, health financing and medicine regulation and harmonisation. Accordingly, the resilience of health systems across the region remains weak in 2022, with low levels of preparedness and response capacities to health emergency and to mitigate their long-term impact. More precisely, the COVID-19 outbreak highlighted the impact of these structural weaknesses and gaps on the resilience of these health systems. The health system and economic reforms have posed several challenges for these immunisation systems to perform to the desired levels and operationalise the needed legal and technical regulations and guidelines for effective programme management. Reorganisation of the primary health care services led to modified roles and responsibilities of the general practitioners and paediatricians in immunisation programme including decrease in number of health care professionals dealing with immunisation. The private sector services have varied levels of involvement in routine immunisation services. It is imperative to note that identified gaps in immunisation coverage have not been systematically addressed leading up to accumulation of cohorts of un - and under vaccinated population groups. In addition, a decreased trust in immunisations in the population has been noticed. The COVID-19 vaccine deployment and vaccination in the region faced similar challenges linked to limited human resources, suboptimal capacities and difficulty in repurposing and redistribution of human resources for vaccination service provision. The scarcity of personal protective equipment and disinfectant products had an important impact in terms of health services disruptions, morbidity and mortality in Mexico.

To face the COVID-19 pandemic, since the beginning of the COVID-19 outbreak Mexico has concluded purchasing agreements with European and U.S. pharmaceutical companies, as well as with Russia and China, and has joined the COVAX mechanism. More than 200 million doses have been administered and the vaccination process is continuing for young children. On the international stage, since the beginning of the COVID-19 outbreak, the Government of Mexico promoted international collaboration within multilateral fora in order to guarantee universal and equitable access to vaccines. In May 2021, Mexico began exporting AstraZeneca vaccines from the Mexican Liomont Plant to Latin American countries, under a joint production agreement signed with Argentina in 2020, to supply around 150 million doses. On September 2021, Mexico's initiative to ensure global access to vaccines led to the UNGA resolution 74/274. However, the local and regional production of vaccine and medical devices remained insufficient and Mexico, with a country of 129 million inhabitants remain overexposed to imports of raw material, vaccines and medicines from abroad, with an increased level of vulnerability and dependency, thus justifying the highest number of authorization of anti-COVID-19 vaccines at global level (more than 10 were authorised).

At regional level, based on the lessons learned from the unexpected pandemic and the downside over the socio-economic system of the region, since 2021 Mexico is actively promoting the ECLAC's plan for self-sufficiency in health matters in LAC.

This intervention is in line with the European Union's response to the COVID-19 crisis, which included a wide range of measures to prevent and fight the COVID-19 outbreak and protect its citizens, ranging from the development and delivery of safe, quality-assured, secure and effective vaccines, to preventive measures aimed at reducing the impact and the spread of the infection and the upscale of the public health structures and functions to better respond to the needs of the COVID-19 patients. In particular, in the field of vaccines the European Commission launched in June 2020 a European strategy to accelerate the development, manufacturing and deployment of vaccines against COVID-19[i] in order to help protect people everywhere and for future COVID-19 like outbreaks. The Commission's vaccine strategy helps companies ramp up their manufacturing capacities at scale and at speed, ensure sufficient supplies for its Member States through Advance Purchase Agreements with vaccine producers, as well as use the flexibility of our rules to speed up the development, authorisation and availability of vaccines. Meanwhile, the Commission has built a diversified portfolio of vaccines for EU citizens at fair prices and vaccination gathered pace across the European Union, and by mid-2022, 86% of adult EU population were fully vaccinated. In order to anticipate the threats of new variants the European Commission has also established the European Health Emergency preparedness and Response Authority (HERA), which aims to prevent, detect, and rapidly respond to health emergencies including those related to the adverse impacts of climate change such as extreme weather events (foods, draughts, increased air pollution or outbreak of vector and water – borne diseases).

In order to support the Central American efforts to increase sanitary self-sufficiency, sanitary regulation is key to ensure the safety of the population and enhance health systems at national and regional level. The current Action aims to contribute to mitigating the impact of COVID-19 in Mexico with positive spill over in the sub-region of Central America and improving the resilience of these countries against health emergencies and disaster –related health risks, mainly through a more coordinated sanitary regulation and oversight. Through this intervention, the EU, in cooperation with partners including the Pan-American Health Organisation (PAHO), will directly enable Mexico to strengthen its health system, improve its capacities and regulatory mechanisms, reinforce its coordination with Central American partners in terms of health security and initiate important health reforms through financial and technical assistance. Dedicated interventions with Central American countries under the coordination of Cofepris will allow a stronger sub-regional coordination and complementary, including joint-training and access to digital platforms, in line with the ECLAC commitments. More precisely, the intervention will support the strategic/policy, legal and regulatory frameworks and enabling environment, and strengthen the regulatory and institutional capacities of Cofepris and support its dynamic role with counterparts from Central America. It will also provide support to a robust preparedness for and implementation in key areas in the deployment of COVID-19 vaccine, facilitating stronger links with the relevant authorities amongst the region and with EU Member States.

This indirectly will also contribute in bringing the region closer to EU norms and standards in key areas such as serious cross-border health threats, vaccination, quality medical products, oversight and regulatory functions, etc. As health is a key contributor for development, these reforms are paving the way for faster, more inclusive and sustainable growth and stability across the region in line with the EU priorities and the UN 2030 Agenda.

The Action's approach is fully right-based in conformity with pillar 1 of the EU-LAC Flagship Roadmap on Human Development (regulatory strengthening), still under discussion but expected to take a holistic approach to social issues and to encompass health, education and social cohesion/fight against inequalities. In particular it reflect its focus on exchanging knowledge and expertise, and building alliances with other organisations (WHO/ *Pan American Health Organization*, IFIs, etc) to ensure sustainable and coordinated results and positive spill overs in the region and in the EU. The Action also responds to the recommendations of the 2022 World Health Summit aimed at addressing simultaneously four key health system functions: governance, financing, resources, and delivery. It aligns with the Global Gateway Strategy in its goal to strengthen supply chains and local vaccines production, although more systemic challenges are to be addressed as well and stronger coordination of the countries involved needs to be ensured. Finally, the proposed action is also aligned to the "European Consensus on Development", in particular the commitment of the EU and Member States to implement the 2030 Agenda. The Action will directly contribute to the Sustainable Development Goals, 3 'good health and wellbeing', 4 quality and education and 17 "partnerships for the goals".

2.2 Problem Analysis

The COVID-19 pandemic highlighted the access inequity to health inputs in Mexico and the region, and the need to ensure more robust regulatory systems and frameworks, with a reinforced cooperation among countries.

Shortly after the health emergency, the disproportionate impact of COVID-19 began to grow in particular in those who are in a situation of greater vulnerability.. The COVID-19 pandemic has developed in Latin America and the Caribbean in a context marked by the matrix of social inequality. This alludes to the presence of a set of axes that structure social inequality, such as gender, ethnicity, race, age or stage of the life cycle and territory, among others, which intersect and reinforce each other, particularly affecting certain population groups and generating exclusion in various dimensions.

In particular, the COVID-19 pandemic has highlighted existing gender inequalities and shed light on several gender implications as a result. Gender discrimination and other social exclusion variables can subject women and other vulnerable groups to a higher risk of infection, limit their access to services and vaccines, undermine national responses, and exacerbate pre-COVID-19 inequities. National lockdowns have resulted in higher levels of domestic violence toward women1. School closures have increased the burden of women in child-care and the gap on un-pain care work between women and men has widened. An increase in household burdens has been especially demanding for women who must work from home[2]. As a result, women have faced even greater barriers to full participation in opportunities for paid work, which has had the added effect of increasing their exclusion from various spheres of public life. Furthermore, in order to balance the care tasks assigned to them and income-generating work, women have increased their participation in part-time work and informal economic activities.

During the first two years of the infection outbreak, the weakness of health systems in Latin America and the Caribbean has conditioned the response to the emergency and the protracted crisis. At the onset of the pandemic, health systems in the region were characterised by a funding shortfall that resulted in a shortage of critical resources for the functioning of interventions and systems of care and to respond to unexpected circumstances. Also, the pandemic highlighted and exacerbated the inequality of the access to vaccines and treatments within and between countries.

The process of vaccination against COVID-19, which began globally at the end of 2020 and in the region at the beginning of 2021, has been marked by significant asymmetries between developed and developing countries, as well as by high heterogeneity among the countries of Latin America and the Caribbean, thus making vaccination coverage in the region too slow to control the expansion of the health crisis. The design, development, production and availability of SARS-CoV-2 vaccines to control COVID-19 has represented one of the most important health challenges in the history of mankind. The COVID-19 pandemic represented a major challenge for both RNAs and National Laboratories of the region because of the need to ensure the quality, safety and efficacy of these new vaccines from diverse technology platforms in a short timeframe.

The American continent is characterised by wide inequalities, not only between sectors of society, gender and minorities but also between countries. Both the health regulation (technical-legal framework) and the agencies that design, supervise and apply it are not exempt from these imbalances. Only in Latin America and the Caribbean, the gap that exists between the main economies of the region (Brazil, Mexico, Chile and Colombia) and the rest of the countries is notorious. On the same continent, highly vigilant National Regulatory Authorities coexist with institutions with less mature regarding technical and scientific capacities. This difference in regulatory and institutional capacities has a direct impact on the integration of evaluation, authorisation and monitoring procedures for products subject to regulation and a regional and equitable access to health supplies. Access to quality medicines is has an important impact on the population's health and well-being, along with a strong impact on social justice and cohesion. A significant driver on both public health and socio - economic inequalities is the impact of environmental degradation and climate change. The impact of the latest is already strongly hitting

[1] *OPS, ONU MUJERES (n.d.) 'El impacto COVID-19 en la salud de las mujeres'. Accessed https://mexico.unwomen.org/sites/default/files/Field%20Office%20Mexico/Documentos/Publicaciones/2020/Julio%202020/Impacto%20COVID%20en%20la%20salud%20de%20las%20mujeres.pdf*

[2] *PAHO, 2021.*

Mexico and the overall Central – America and the Caribbean, and it's not foreseen to decrease in the coming decades. Investments to increase resilience to the impact of climate change and environment has proved cost efficient (according to WHO).

Sanitary regulation is highly complex, because in addition to using the legal sciences to correctly determine its field of application, it has technical elements from the biological, chemical and medical sciences as a background to guarantee that products for human consumption do not generate health risks. Only in pharmaceutical products, health regulation ranges from conducting the clinical research phase to post-marketing surveillance of drugs and vaccines. Vaccines must undergo extensive characterisation and analysis. This involves having knowledge and carrying out special procedures for its manufacture, control, regulation, authorisation and batch release. A challenge faced by the regulatory authorities and the productive sectors subject to health regulation is the absence of human capital trained in regulatory sciences, which generates various problems of efficiency in public health policies governance. These include the difficulty in recruiting specialised personnel, long learning curves, since there is little theoretical material to guide those who join activities related to health regulation, as well as a high dependence on personnel who have acquired their knowledge in a practical way, which makes generational change difficult both in health agencies and in sectors subject to regulation. To better respond to these issues, Cofepris has established a Regional School of Sanitary Regulation, which it is expected to offer various postgraduate studies and training in regulatory sciences (diplomas, specialties, master's degree) both face-to-face and online. These studies are oriented both for personnel who are already working in health regulation, either in a government agency or in the industry, but also for personnel recently graduated from bachelor's degree who are looking to start their career in the health area. The project will promote the equal participation of women to the Regional School of Sanitary Regulation, by establishing a quota making sure that this criteria is being respected.

The National Regulatory Authorities of the Americas face the common challenge of achieving the goals and objectives of their countries´ programs and projects within a framework of transparency, promptness, technical and scientific support, in order to respond to the public health expectations of our populations. Improving the strategic management of regulatory systems is essential to increase their response capacity to health emergencies, with a special focus on the rational and efficient use of resources, technology, and innovation. In a context of increasing globalisation of the pharmaceutical industry, rapid advances in health sciences, and the need to increase the capacity to respond to health emergencies, it is essential to increase international cooperation between the regulatory systems to facilitate the implementation of an effective protection against sanitary risks.

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

The overall responsible authority at federal level in Mexico is the Mexican Regulatory Authority - Cofepris, while at State level, there are entities responsible for planning and execution. The main beneficiaries of the Action will be Cofepris. It is expected that Regulatory Authorities of the Central American countries involved in the project and their staff, in particular women, will also benefit from the project. Specifically, all these institutions are responsible for regulating, monitoring and verifying pharmaceutical products and ensure health harmonisation. In view of future financing, the Mexican Ministry of Finance, together with international development financial actors and the Mexican private sector are crucial to ensure sustainable and meaningful results. The Ministry of Finance is the main entry point for the development and approval of successful, bankable projects, as well as for the coordination of institutional steps towards sustainable activities. The private sector is largely the main investor in health infrastructure - and the segment that can ensure an increasing quality of health service delivery in Mexico and the Central American region. In particular, stock exchanges and large companies specialised in pharmaceutical products and vaccines could be important stakeholders for the development of an enabling environment for sustainable health finance in Mexico and in the region.

3 DESCRIPTION OF THE ACTION

3.1 Objectives and Expected Outputs

The **Overall Objective (Impact)** of this Action is to support the strengthening of Mexico regulatory system for medicines and vaccines and enhance regional sanitary self-sufficiency (EU4Health); this is part of the preventive measures to counteract increased exposure to diseases related to disasters.

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

SO1. enhance efficiency, transparency, performance, innovation and sustainability of the Regulatory Authority in Mexico (Cofepris)

SO2 promote the modernisation of public policies, legislations, processes and regulatory frameworks related to Cofepris' mandate, while ensuring the adherence to the WHO Global Benchmarking Tool (GBT), the WLA performance evaluation framework and WHO's norms and standards as well as International Conference on Harmonization (ICH) guidelines.

SO3. support cross-national and regional regulatory systems in Central America, guaranteeing quality medicines and medical devices, as well as regulatory harmonisation and reliance, while ensuring the reference role of Cofepris.

3) Results (Outputs)

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

Contributing to **Outcome 1 (Specific Objective 1):**

1.1 Improved Cofepris' capacity in planning, monitoring, policy development and digitalisation, integrating WASH environment, logistics, climate and other relevant sectors, with a specific focus on inspections, scientific evaluation and safety of medicines;

1.2 Cofepris' has enhanced access to European methodologies, technical and scientific advancements, including in climate and environment related regulations and coordination mechanisms;

1.3 The Regional School of Sanitary Regulation (ERRS) successfully runs the first specialisation on medicines and vaccines regulation and the second specialisation is in place. Both specialisation incorporate disaster – related risks assessment (including for vulnerable groups);

1.4 Health personnel from regulatory authorities of Central American countries have a structured and regular access – physical and virtual - to the Regional School of Sanitary Regulation in Mexico based on Memorandum of Understanding agreed between partners at least for the duration of the project

Contributing to **Outcome 2 (Specific Objective 2):**

2.1 Enhanced availability of policy, legal and regulatory framework assessments in Mexico and Central America based on WHO Global Benchmarking Tool (GBT);

2.2 Improved technical and administrative capacities for health legislation drafting and assessment, with a specific focus on sanitary regulation in Mexico and Central America;

2.3 A state of play with an update on the regulatory situation of NRAs, gaps, and potential for regional collaboration is in place and a regional strategy of regulatory convergence for Mexico is adopted;

2.4 Cofepris's regulatory mandate is upscaled, and its Global Benchmarking Tools (GBT) updated in order to upscale its ranking in the list of WHO Listed Authorities framework – WLA.

Contributing to **Outcome 3 (Specific Objective 3)**:

3.1. Improved technical capacities and involvement of representatives from the staff of the Central American regulatory authorities with regard to the design and implementation of harmonised regulatory frameworks;

3.2. Improved cross-national coordination in health medicine security/emergency and in preventing and dealing with unexpected health medicine threats, including medicine surveillance / pharmacovigilance;

3.3 Enhanced relations of Cofepris with the EU Member States (MSs) regulatory national authorities, based on memoranda of understanding giving special attention to comparative legislation, and comparative implementation processes, in line with ICH guidelines.

3.2 Indicative Activities

Contributing to **Specific Objective 1**:

1.1 Technical support and exchange of experience with NRAs from the EU MSs to enhance the Cofepris' capacity in planning, monitoring and strategy definition – including support and guide to the modernisation of policies, legislations and implementation processes taking most recent climate projections and expected health impacts on board, and with a specific focus on inspections, scientific evaluation and safety of medicines.

1.2 Technical exchanges with EU MS NRA to support Cofepris in its functions as a regulatory agency at national level and to play an active role at sub - regional level as a reference Authority

1.3 Support to the technical and administrative capacity of the staff, and the study plan of the Regional School of Sanitary Regulation, including exchange and training for the School staff, in particular women,

1.4 Strengthening of Cofepris' technical-scientific capabilities by providing access to the EU digital platforms such as the European Pharmacopeia, European reference resources, European programs of standardisation, and online courses, also giving attention to adequate medical waste management, using standards and guidelines developed by WHO including the 2018 guide safe management of wastes from health care activities.

1.5 Contributing to the digital transformation of Cofepris by supporting the unification of its data bases in one operative system, with an access for Central American countries

1.6 Fostering the participation (mostly virtual learning with ad hoc scholarships) of civil servants, in particular women, specialised in sanitary regulation from the Central American national regulatory authorities and health ministries in postgraduate specialisation in health regulation at the Regional School of Sanitary Regulation in Mexico and promote structured exchanges between Mexico and Central American countries

1.7 Exchange of best practices and technical assistance – including through staff mobility - on an institutional framework and high-standard for sanitary regulation, with specific exchanges with EU MSs NRAs based on an annual work programme

1.8 Training and coaching of available staff (Cofepris and from regulatory authorities from Central America) on health security and health emergency coordination at federal, state and municipal level

Contributing to **Specific Objective 2**:

2.1 Revision of the strategic, legal and regulatory framework, with recommendations for improvements based on GBT (WHO Global Benchmarking Tool)

2.2 Exchange of best practices and technical support for Cofepris' staff on health legislation drafting and assessment with a specific focus on health financing

Contributing to **Specific Objective 3**:

3.1 Development of a state of play with an update on the regulatory maturity of National Regulatory Authorities (NRAs), gaps, and potential for regional collaboration is in place

3.2 Exchange of best practices, including through staff mobility, for Central American partners and with EU regulatory authorities to strengthen cross-national and regional sanitary regulation and joint response to health-related crisis and promote regulatory harmonization and Reliance

3.3 Strengthened relations with EU MSs Regulatory Authorities on laboratory practices, marketing authorisation functions, including registration of products in emergencies, timeline for processing marketing authorisation and relevant tracking systems

3.4 Cross-national collaboration in Central America to promote cross-national coordination in health emergency and in dealing with unexpected health threats, including surveillance.

3.3 Mainstreaming

Health security

The final objective of this Action is to support Mexico in the implementation of specific actions contributing to the health security, coordination and strengthening, with a positive and direct impact on Central American countries. This will be achieved through reinforced structures and capabilities of the regulatory authorities of the region to better ensure the prevention of sanitary risks and the enhancement of sanitary resilience in times of crisis.

Environment and Climate change

In cooperation with *Pan American Health Organization* (PAHO) Washington and Geneva when relevant, PAHO Mexico will ensure that the management of environmental effects, including any environmental analysis, is carried out in accordance with the environmental processes and requirements of PAHO. Particular attention will be given to the issue of medical waste management in the context of this Action, if relevant, using existing standards and guidelines developed by WHO including the 2018 guide *Safe management of wastes from health-care activities* as detailed before.

The Environment Impact Assessment (EIA) and the Strategic Environmental Assessment (SEA) will not be implemented

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 not at risk (climate risk will be addressed as part of an EIA for outputs 1.1 – 2.5.

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 gender mainstreaming, as primary means to achieve gender equality has been integrated in the design of this Action and will be a substantive objective throughout the implementation of the activities, including the promotion of gender equality in staff exchange and training.

Gender-responsive components will be integrated into the planning and project management when and as relevant. Activities implemented in the context of this Action will be gender sensitive and the specific needs of women as part of the different stakeholder groups will be taken into account through this Action also ensuring that women

take part in the relevant decision-making mechanisms whenever possible. Particular focus will be put on collecting gender and age disaggregated data as part of the monitoring and evaluation of this action across the set of indicators listed in the log frame

In general, the EU is committed to gender mainstreaming in all policies and actions as a responsibility for all.
In this action, three minimum standards will be applied:

1. Conducting and using updated gender analyses to inform decision-making on future action and integrating these into all relevant activities;
2. Applying gender-sensitive and sex-disaggregated indicators and statistics to monitoring and evaluation;
3. Giving robust reasons, based on the findings of the gender analysis, to substantiate any activity deemed not to contribute to gender equality.

Human Rights

By promoting extended access to safe, secure and effective quality medicines and vaccines, the Actions aims at promoting the human right approach and enhance health for all, including the most vulnerable groups. Human Rights Based Approach (HRBA) is integrated in the design of this Action and will represent a cross-cutting issue throughout its implementation. *Pan American Health Organization* (PAHO) commits to actively engage in and promote human rights, gender-responsive and vulnerable groups approaches on projects funded through this action which is in line with WHO's prioritization of the SDG "Leave No One Behind" agenda.

Disability

Although disability is not directly related to the scope of the Action, all activities have an inclusive approach for vulnerable groups, which are more exposed to the consequence of a non-regulated system of medicine and vaccines. All material and outcome from this intervention will be accessible for people living with disabilities, especially for people with earing and visual impairments.

Democracy

This Action, while improving access to safe and effective quality medicines and vaccines, aims at promoting social justice and ensuring access to health rights, which in turn promotes democratic values and principles, independently of any political views. By promoting transparency and higher standards of governmental institutions, this Action will strengthen the trust of citizens in the Government and its staff.

Conflict sensitivity, peace and resilience

By strengthening the regulatory capacities and improving convergence and harmonisation, the Action will strongly promote sanitary resilience of the region and fostering a better reaction to external challenges, which could affect the overall stability and peace of the region if not properly addressed. It will also ensure the provision of better services for the citizens, leading to recognised and valued citizens with an improved wellbeing and increased protection from social conflicts.

Disaster Risk Reduction

Fostering preparedness to sanitary emergencies and enhancing sanitary resilience will improve the capacity of countries to face unexpected challenges and counter the effects of sanitary crises, including environmental ones.

Other considerations if relevant

This Action mainstreams digital transition approach, by addressing digitalisation as a main enabler to achieve progress on the harmonisation and coordination of Agencies in Mexico and Central America. Digitalisation is expected to boost medicine harmonisation and rapid alert, as well as to enhance dialogue among regulatory entities from the sub region and the European Union, with emphasis on interoperability.

Inequality

As per Inequality Marker, the action is labelled as I-0 as it is relevant for inequality reduction only in terms of final impact on the population. The population, especially the most vulnerable groups and regions of Mexico will benefit for an increase quality and surveillance of the medical products and devices, and rely on more efficient institutions able to promote a better health and wellbeing for All, both in times of crisis and in normal conditions.

3.4 Risks and Lessons Learnt

Category	Risks	Likelihood (High/ Medium/ Low)	Impact (High/ Medium/ Low)	Mitigating measures
	Changing political landscape	H/M	H/M	Strong engagement with and involvement of the Cofepris and regulatory agencies from Central America and the European Union leadership in the implementation of the Action to ensure ownership and buy-in on the proposed activities.
	Continuation of the COVID-19 outbreak impacting the implementation of the Action and availability of beneficiary authorities to participate in activities	H	H	As the organization leading the COVID-19 pandemic response at regional level, PAHO will continuously monitor the COVID-19 situation across the region, identify potential impact on the Action and draw mitigation plans to address potential issues in close coordination and consultation with the European Commission.
	Inadequate in-country governance and coordination of various government stakeholders and partners to respond to health crisis and ensure coordination	H	H	Ensuring the coordination of COVID-19 vaccination within the overall structure of beneficiaries' COVID-19 response headed by the Ministries of Health. The coordination by senior government officials of various stakeholders will be critical for the success of the Action
	Absorptive capacity issues by the *Pan American Health Organization* (PAHO)	H/M	H/M	Strong planning to ensure smooth and timely implementation, adequate staffing for project management in the PAHO office Mexico, recruitment – if and when appropriate of consultants and coordination with PAHO regional office for providing dedicated support to the MX team to ensure that mitigating actions can be implemented in case of emergency.
	Unavailability of relevant professional human resources required for the effective implementation of the Action at the Pan American Health Organization (PAHO)	M	M	The *Pan American Health Organization* (PAHO) Mexico will draw on existing capacities in Health and Health Emergency Hub and its Health Financing Office and existing networks of expertise while expanding selections processes for technical assistance based on the process used for the identification/selection of PAHO experts/consultants, ensuring a roster of qualified professionals. PAHO Mexico also has a large pool of experts/consultants in drug harmonization ready to be deployed
	Risk of corruption related issues in the health sector	M	M	Specific anti-corruption and oversight measures included in PAHO relevant procurement and other financial arrangements signed with central authorities and service providers.
	Risk of natural disaster or any other type of disaster affecting the region and hampering the smooth	L	L	A contingency plan will be established in case of emergency to take into account the context and

	implementation of the activities			challenges and design adequate measures to tackle unexpected situations.
	Countries of Central America and the EU are not fully involved in the Action and do not cooperation actively for its implementation.	L	L	A MoU will be developed and signed at the beginning of the Action by participating countries and EU MS Regulatory Authorities to ensure their active commitment and foster their participation and involvement during the project.

Lessons Learnt:

This Action is innovative at two levels: first, it is the first large initiative financed by the European Union in Mexico in the health sector that is being supported and completed by a regional project – still under definition - at regional level, aimed at supporting the LAC sanitary plan. Second, the action proposes a comprehensive approach, including coordination with EU MSs agencies and stakeholders with a sub - regional approach to enhance coordination and overcome barriers to decision making in volatile environments. The following lessons were learnt during the consultations and design of these actions.

- Define activities at the appropriate level depending on the scheme of institutional responsibilities.
- Create structured alliances based on memorandum of understanding with determined stakeholders that ensure leadership throughout implementation and ownership of results for their sustainability at medium and long term
- Improve coordination and communication at results level among EU Member States working on health in Mexico to avoid duplication, and ensure active participation to Outcome 4 from the design phase
- Promote a cross-sector approach that fosters sustainable and technical alliances among countries of the region at all levels, with a clear role of the different partners

Sustainability

As the leading international organisation for global health in the region, the *Pan American Health Organization* (PAHO)'s work is driven by demand from the beneficiaries, which contributes in ensuring the sustainability and ownership of its actions, programmes, strategies and other initiatives. In the context of this Action, PAHO is committed in ensuring this sustainability and ownership by closely coordinating this initiative with the health authorities in the Mexico and the concerned countries, in particular in its role of coordination of the Pan American Network for Medicine Regulation (*Red Panamericana de Armonizacion de la Reglamentacion Farmaceutica* – PARF). The Action will complement the regional health activity implemented by PAHO Washington in parallel over the same timeframe as well as the initiatives that will be developed in the area of public health and sanitary crisis response and prevention under the EU-Mexico Joint Fund (Development in Transition project) under implementation. The Action will combine central-level activities (in Mexico) sub –regional (with Central America) and bi-regional activities (with the Europea Union) with the focus put on providing support with the highest impact of citisens' health and wellbeing, taking account of evolving needs and synergies with other partners. The Action will more particularly ensure:

- Ownership by beneficiaries – The Action activities will be implemented in close cooperation with relevant governmental institutions (Cofepris and reference in the other countries), and with their active involvement at every stage of the project. This will ensure the beneficiaries' ownership of the Action outcomes and sustain them after the completion of this initiative.

- Alignment with beneficiary needs and priorities expressed by ECLAC Members. The Action has been developed on the basis of assessments performed in coordination with beneficiary authorities and relevant stakeholders. These assessments have identified shortcomings and priority needs from partners that have been involved in the definition of the Action objectives, activities and expected results.

Long-term capacity building – Training, capacity and institutional building are integral part of this Action and will aim at developing long-lasting capacities and partnerships between the relevant authorities at Mexican, sub - regional and bi - regional levels. This shall enable the continuation of the Action after the end of the EU financing. This will be done through the establishment of partnership technical agreements (memoranda of understanding) that will cover training activities, technical support and the dissemination of best practices. Creating a community of practice –

Sharing experiences and peer-to-peer learning between the participating beneficiaries will help to create a community of practice that will remain in the region beyond the duration of the Action. The documents and outputs developed within the Action will be open for access in accordance with the *Pan American Health Organization* (PAHO) Open Access Policy. This will facilitate further dissemination of better practices in the region.

3.5 The Intervention Logic

Due to its size, population and geo-political position, Mexico is an important global actor regarding health related issues and health security and a key player in Central America to pursue an ambitious health sector modernisation, including the harmonisation of drugs and regulation of the health sector and the promotion of health resilience and security measures. Mexico has also actively engaged itself at global level in the recent years to promote sanitary self-sufficiency measures in view of future pandemics and health challenges and stronger cross-national coordination in Latin America. However, despite its leading role in global fora, Mexico requires extended technical and financial assistance to be able to concretize its ambitions.

The underlying intervention logic for this Action is that the modernisation of the regulatory framework in Mexico, including medicine and medical devices streamlining and the strengthening of capacities of the concerned institutions, will help increasing efficiency in governance of regulatory and oversight institutions, enhancing health resilience and security, such as preventive measures to counteract increased exposure to diseases related to disasters, and promoting social inclusion/cohesion with a long-term impact on the reduction of inequalities and the promotion of quality services for All. This will at the same time help fostering productivity and supporting economic growth in the sub-region and promote technical modernisation and innovation. This approach is in line with the 2030 Agenda for Sustainable Development and aims at achieving its goals in Mexico and in Central America. The support to the modernisation and digitalisation of Cofepris and its services will benefit neighbouring countries allowing a better implementation and enforcement of the health and security policies and legislations with regard to medicines and medical devices, for the provision of more tailored, efficient and effective services (including the ones adapted to climate projections reducing the vulnerability and / or exposure to expected risks through improved health information systems) and quality medicines to the population. This in turn will support social justice and quality governance increasing the trust in the institutions and promoting social cohesion. It will also have a positive impact on the fight against corruption by rationalising processes and formalising responsibilities. This in turn, aims at promoting human dignity, hope and democracy derived from having a solid medicine regulatory system and valuable state institutions, and contributes to building and maintaining social peace and security and improving social, community and individual resilience.

The overall objective of the proposed Action is to support Mexico and Central America strengthening and harmonising their regulatory frameworks and enhancing regional sanitary self-sufficiency, to better respond COVID-19-alike threats and ensure high quality standard for medicine and their access to all. (EU4Health).

In particular the Action aims to achieve the following Specific Objectives:

SO1. To enhance efficiency, transparency, performance, innovation and sustainability of the Regulatory Authority in Mexico (Cofepris),
SO2 To promote the modernisation of public policies, legislations, processes and regulatory frameworks related to Cofepris' mandate, while ensuring the adherence to the WHO Global Benchmarking Tool (GBT), the WLA performance evaluation framework and WHO's norms and standards, as well as ICH guidelines.
SO3. To support cross-national and regional regulatory systems in Central America, guaranteeing quality medicines and medical devices, as well as regulatory harmonisation and reliance, while ensuring the reference role of Cofepris.

This would imply to facilitate the strengthening of the Cofepris' mandate and its efficiency as catalyst for health regulatory reform and harmonisation; strengthen policy and legislative frameworks for sanitary regulation and harmonisation; in coordination with the regional EU-LAC partnership on vaccine production and health systems resilience, building partnerships for development with competent partners to strengthen the overall response to emergency crisis and enhance regional sanitary self-sufficiency and regulatory harmonisation, as well as enhancing regulatory harmonisation, promoting cross-national sanitary cooperation and partnerships, and fostering preparedness and joint-response to sanitary emergencies. Digitalisation has an important role in the project, as it fosters the modernisation of Cofepris to enhance regulatory harmonisation and boost efficiency. The upscale of

Cofepris will help the Agency to be certified by WHO and become a WHO Listed Authority. This certification is a new classification of regulators that guarantees the functionality and quality of the regulatory functions Furthermore, the adoption of EU e-methodologies and systems will provide a faster and more efficient tracking of the sanitary regulation and allow stronger and quicker coordination with partners on sanitary matters. Consultations with the civil society and the private sector during the project implementation will allow a stronger partnership for efficiency and transparency. The use of European methodologies and systems will promote the EU and facilitate exchanges and technical connections.

In particular, the third objective will foster strategic relations with EU MS regulatory institutions to enhance efficiency, monitoring and implementation of sanitary regulation policies. It would also allow to strengthen relations in areas of common interest addressing for example prevention, security and drug though exchange of best practices on the development of more efficient institutions, processes, mechanisms, policies and legislations, or the promotion of transparency and safety in medicine harmonisation, and a strong emphasis on security, quality and consumer protection. With regard to the region, the third objective will foster coordination and convergence of cross-national and regional regulatory systems in Central America, guaranteeing quality medicines and medical devices, as well as regulatory harmonisation and reliance, while ensuring the reference role of Cofepris in the region in line with the ECLAC commitment.

The Action will more specifically aim at supporting Mexican Cofepris' capacity in planning, monitoring, regulating, surveillance and strategy definition and providing adequate support in terms of best practices and exchanges. Concretely, the Action will help strengthening Cofepris and increase processes and standard for medicinal regulatory, marketing authorisation and laboratory practices, through specific exchanges with EU MSs and Central America national health institutions. This will be done in full cooperation with the EU MSs already active with Cofepris in the area of regulation and exchange of best practices for regulatory governance, such as for example the Danish Regulatory Medicine Agency, and with the EU MSs that will be active during the duration of the project. This could be achieved with joint workshops, or exchange of best practices and study visits to enhance partnership with MSs and promote sustainability in results. It will also contribute to strengthen the actions that Mexican regulatory authorities are taking in preparation of the assessment by the World Health Organisation (Global Benchmarking Tool) and in particular to improve certain areas such as the drafting of the Cofepris Institutional Development Plan and the regulatory framework update. This will be achieved by providing technical assistance to the National regulatory authority in Mexico; assessing skills gaps in, particularly in regulatory sciences, and consequently; strengthening the Mexican based school on sanitary regulation (e.g. by supporting the participation of health system public servants from partner institutions to the school training and specialisation courses for medicine and vaccine regulation) and tertiary education in alignment with Erasmus +, fostering technical relations with EU MSs regulatory agencies and institutions at national level, and improving public institutions' capacity to prevent and face emergency crisis and support Cofepris capacities for coordination. The civil society will be included in the project throughout the whole project cycle, as the project support the promotion of society organisations participation in policy making and monitoring of implementation, as well as stronger links with the private sector in the area of vaccine and drug production. It also aims at increasing awareness and citizens' engagement around global health challenges, health access for all and priority areas for action leaving no one behind.

The Action will include the assessment and empowerment of the Regional School of Sanitary Regulation of Mexico under Cofepris (ERS) so that it can successfully respond to its mandate to run the first specialisation of health regulation in the sub-region and help upscaling the competence of specific regulatory sanitary profiles, not yet available.

The Action will not only strengthen the regional dimension of regulation and create harmonisation of tools, but also create new partnerships with the EU MSs. Finally, enhancing the regulatory framework will incentivise Foreign Direct Investments and facilitate private investments, while also ensuring timely access to effective, quality vaccines and medicines to the population.

In order to ensure the best support to Cofepris and its regional partners, this intervention includes an assessment of the strategic and policy frameworks (SO1), with a specific focus on health financing. It also includes the preparation of adequate recommendations for improvements, along with specific technical assistance for drafting, monitoring and evaluation of health legislation and regulations. This includes the preparation of a state of play with an update on the regulatory maturity of National Regulatory Agencies (NRAs), gaps, and potential for regional collaboration is in place and a regional strategy of regulatory convergence for Mexico, Central America. To achieve these objectives, the Action will build on lessons learnt during the COVID-19 outbreak and rely on a regional approach

based on activities benefiting all beneficiaries to maximise impact across the region. Through the adoption of this combined approach covering all beneficiaries in synergy with other initiatives, the Action will make it possible to provide help that is needs-driven, differentiated, and cost-effective due to economies of scale. At the same time will foster a strengthened Mexican role in coordination and response, and a strengthened links with the EU MSs institutions.

An Action plan will be developed during an inception phase of the project (1 month duration). The Action plan will be based on the beneficiary needs assessments performed by the *Pan American Health Organization* (PAHO) Country Team in coordination with its Regional and Central America Offices in Washington that will be in charge of a regional EU-funded health project with important synergies and areas of cooperation, and in consultation with the sub-regional EU Delegations and beneficiary authorities in Mexico (Cofepris) and Central America. The Action Plan will cover all the two strategic objectives and will revolve around the priority country-specific involvement identified out of the list under section 3.2 hereafter. The action plans and its regular revisions will ensure regional coherence and cohesion while accounting for specific contributions of the different partners in the region. The Action plan, based on the inception report, will be reviewed by EU Delegation in Mexico, and approved by the Steering Committee (see section 5.1. hereafter). Indicators and targets in the log frame will be further refined and tailored to the beneficiaries' contexts by the implementing partner in cooperation with the relevant stakeholders following the inception phases.

The main stakeholder of the Action is Cofepris. The regional regulatory authorities of Central American Countries and the EU MS regulatory agencies will also be involved. The population of Mexico will benefit from better regulatory frameworks and increase sanitary self-sufficiency and coordination as advocated in the EU-LAC Roadmap. State congress, municipalities, private sector working in the health sector, think-tanks and civil society organisations will be associated to the Action, along with EU MSs regulatory agencies, for overall support to health security and health strengthening.

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 (maximum 10)	Indicators (@): (at least one indicator per expected result)	Baselines (values and years)	Targets (values and years)	Sources of data	Assumptions
Impact	To support Mexico strengthening its regulatory systems for medicines and vaccines and enhancing regional sanitary self-sufficiency	- Universal Health Coverage (UHC) index (GERF 1.27 SDG 3) - International Health Regulations (IHR) capacity and health emergency preparedness (SDG 3.d.1) - Proportion of the target population covered by all vaccines included in their national programmes (SDG 3.b.1)- Cofepris advances in the WLA performance evaluation framework. -Quality standards for sanitary regulation in Mexico and central America are improved.	To be added at the inception phase	To be added at the inception phase	-Annual report of Cofepris -Annual and regular reports of PAHO/WHO -Official publications on Cofepris webpage -Reports from the General Heath Council (Consejo de Salubridad General) -Reports from Central American Regulatory Authorities	
Outcome 1	1. Enhance efficiency, transparency, performance, innovation and sustainability of the Regulatory Authority in Mexico (Cofepris),	1.1 Number of innovative and high performing changes introduced by Cofepris in light of WHO's recommendations and indicators. 1.2 The average time for Cofepris to process a sanitary	To be added at the inception phase	To be added at the inception phase	-Annual report of Cofepris -Official publications on Cofepris webpage - As per WHO assessments (GBT/WLA).	

		authorisation is substantially reduced	To be added at the inception phase	To be added at the inception phase		
Outcome 2	2. Promote the modernisation of public policies, legislations, processes and regulatory frameworks related to Cofepris' mandate, while ensuring the adherence to the WHO Global Benchmarking Tool (GBT), the WLA performance evaluation framework and WHO's norms and standards, as well as ICH guidelines.	2.1 Number of policies, strategies and regulatory frameworks related to medicine and medical devices under Cofepris' mandate revised on the basis of international standards, practices and guidelines. 2.2 Number of policies, strategies and regulatory frameworks related to medicine and medical devices under the responsibility of the Regulatory Authorities revised in partner countries from the sub region	To be added at the inception phase	To be added at the inception phase	-Annual report of Cofepris -Official publications on Cofepris webpage - As per WHO assessments (GBT/WLA).	
Outcome 3	3. To support cross-national and regional regulatory systems in Central America, guaranteeing quality medicines and medical devices, as well as regulatory harmonisation and reliance, while ensuring the reference role of Cofepris.	3.1 Number of collaboration agreements signed by Cofepris with the EU National Regulatory Authorities (NRAs) 3.2 Number of joint-response strategies designed and revised for each country	To be added at the inception phase	To be added at the inception phase	-Cofepris Reports -Reports from the Central American Regulatory Authorities	

Output 1 **relating to Outcome 1**	Improved Cofepris' capacity in planning, monitoring, policy development and digitalisation	1.1.1 1.1.1 Number of staff at Cofepris trained by the EU-funded intervention with increased knowledge and or skills in planning, budgeting, monitoring and policy definition 1.1.2 Number of processes digitalised by Cofepris with support of the EU-funded intervention	To be added at the inception phase	To be added at the inception phase	-Internal reports at Cofepris -Annual Report of Cofepris -Administrative data of Cofepris	
Output 2 **relating to Outcome 1**	Cofepris' has enhanced access to European methodologies, technical and scientific achievements	2.1.1 Number of European methodologies made available at Cofepris under the EU-funded intervention 2.1.2 Number of European methodologies made available at Cofepris under the EU-funded intervention 2.1.3 Number of European technical and scientific achievements endorsed by Cofepris under the EU-funded intervention 2.1.4 Number of European methodologies and tools made available in Central American countries under the EU-funded intervention	To be added at the inception phase	To be added at the inception phase	-Internal reports at Cofepris -Annual Report of Cofepris -Administrative data of Cofepris - Regular Reports of PAHO	

		2.1.5 Number of methodologies available at Cofepris for its Central American partners 2.1.6 Number of methodologies available at Cofepris for its Central American partners				
Output 3 **Relating to Outcome 1**	The Regional School of Sanitary Regulation of Mexico under Cofepris (ERRS) successfully runs the first specialisation in medicines and vaccines	3.1.1 Number of permanent staff from the Regional School of Sanitary Regulation (ERRS) trained under the EU-funded intervention, disaggregated by sex 3.1.2 Number of staff from Regulatory Agencies from Central America attending in the specialisation in health regulation at the Regional School of Sanitary Regulation (ERRS), with the support of the EU-funded intervention, disaggregated by sex	To be added at the inception phase	To be added at the inception phase	-Internal reports at Cofepris, including reports from the Regional School of Sanitary Regulation -Annual Report of Cofepris -Administrative data of Cofepris	
Output 4 relating to Outcome 1	Health Personnel from regulatory authorities of Central American countries have a structured and regular access – physical and virtual – to the Regional School of Sanitary Regulation based on a Memorandum of Understanding agreed between partners at least for the duration of the project	4.1.1 Number of participants from Central American Regulatory Authorities to the specialisation course of the ERRS, under the EU-funded intervention, disaggregated by sex	0	To be added at the inception phase	-Internal reports at Cofepris -Annual Report of Cofepris	

Output 1 **relating to Outcome 2**	Enhanced availability of policy, legal and regulatory frameworks in Mexico and Central America based on WHO Global Benchmarking Tool (GBT), as well as ICH guidelines.	1.2.1 Number of assessments available on current strategic, legal and regulatory frameworks in Mexico, revised or developed under the EU-funded intervention 1.2.2 Number of assessments available on current strategic, legal and regulatory frameworks in Central America, revised or developed under the EU-funded intervention	To be added at the inception phase	To be added at the inception phase	-Internal reports at Cofepris -Reports of the Central American Regulatory Authorities	
Output 2 **relating to Outcome 2**	Improved technical and administrative capacities for health legislation drafting and assessment, with a specific focus on health financing in Mexico and Central America	2.2.1 Number of staff trained in health legislation drafting and assessment in Mexico, with specific focus on women 2.2.2 Number of staff trained in health legislation drafting and assessment in Central America, with specific focus on women	To be added at the inception phase	To be added at the inception phase	-Internal reports at Cofepris -Annual reports of the Central American Regulatory Authorities	
Output 3 relating to Outcome 2	A state of play with an update on the regulatory situation of NRAs, gaps, and potential for regional collaboration is in place and a regional strategy of regulatory convergence for Mexico and Central America is adopted	3.2.1 Number assessments revised, available and adopted on the regulatory situation of NRAs, gaps with the support of the EU-funded intervention 3.2.2 Number of updates to the state of play available with the support of the EU-funded intervention	0 0	To be added at the inception phase	Internal reports at Cofepris	

Output 4 related to Outcome 2	Cofepris's regulatory mandate is up scaled, and its Global Benchmarking Tools (GBT) updated in order to upscale its ranking in the list of WHO Listed Authorities framework – WLA	4.2.1 Ranking of Cofepris in the list of WHO Listed Authorities Framework	To be updated during the formulation phase	To be added at the inception phase	- Annual Report of Cofepris - Reports of WHO - WLA	
Output 1 **relating to Outcome 3**	Improved technical capacity and involvement of representatives from the staff of the Central American regulatory authorities in the design and implementation of harmonised regulatory frameworks	1.3.1 Number of staff from Central American Regulatory Authorities trained by the EU-funded intervention with increased knowledge and/or skills in the design and implementation of harmonised regulatory frameworks	0	To be added at the inception phase	-Annual and regular administrative reports of the Central American Regulatory Authorities - Regular reports of PAHO	
Output 2 **relating to Outcome 3**	Improved cross-national coordination in health security/emergency and in preventing and dealing with unexpected health threats, including surveillance in Mexico and Central America	2.3.1 Number of events and study visits organised by the EU-funded intervention to enhance regional cooperation and cross-national coordination in health security/emergency and in preventing and dealing with unexpected health threats 2.3.2 Joint Emergency Plans designed, adopted and available for each country	0	To be added at the inception phase	Cofepris regular reports and data Annual and regular reports of the Central American Regulatory Authorities	
Output 3 **relating to Outcome 3**	Enhanced relations of Cofepris with the EU MSs regulatory national authorities, based on memoranda of understanding giving special attention to comparative legislation and	3.3.1 Number of Memoranda of Understanding signed by Cofepris with EU MSs national regulatory authorities with the support of the EU-funded intervention	0	To be added at the inception phase	-Cofepris annual and regular reports -Reports from the EU MSs national	

	comparative implementation processes				regulatory authorities	

4 IMPLEMENTATION ARRANGEMENTS

4.1 Financing Agreement

In order to implement this Action, it is not envisaged to conclude a financing agreement with the partner country.

4.2 Indicative Implementation Period

The indicative operational implementation period of this Action, during which the activities described in section 3 will be carried out and the corresponding contracts and agreements implemented, is 48 months from the date of adoption by the Commission of this Financing Decision.

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

4.3 Implementation Modalities

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

4.3.1 Indirect Management with a pillar assessed entity

This Action may be implemented in indirect management with the *Pan American Health Organization* (PAHO) Mexico office with support from its Regional Office and in collaboration with the PAHO offices based in Central America, selected by the Commission's services using the following criteria:

- In terms of nature of the Action, the entity has demonstrated technical experience in implementing EU funded actions;
- The entity's leadership in working in the health sector and in the region is recognised at national and regional level
- Capacity to identify and create alliances with relevant national and international stakeholders and develop a solid health network basis to ensure sustainable results in view of policy changes in Mexico and in the region of Central America, in particular in the framework of the already existing network for the harmonization of medicine regulation (Red Panamericana de Armonizacion de la Reglamentacion Farmaceutica – PARF);
- Well-developed relation and sound partnership with the beneficiary of the Action (Cofepris), with activities ongoing that are complementary with the interventions foreseen under this Action;
- The entity's know-how and expertise in the health sector, demonstrated through previous successful projects and initiatives, both at national and regional level.

The implementation by the *Pan American Health Organization* (PAHO) entails the implementation of the indicative activities under this Action. The expected results are to contribute to the strengthening of the health sector, resilience and security in Mexico and in the Central America, fostering coordination among agencies with the scope to promote harmonisation and cooperation within Central American and with the EU, in line with European and other international frameworks.

In case the envisaged entity would need to be replaced for justified reasons, the Commission's services will select a replacement entity using similar criteria, giving priority to EU Member States cooperation agencies involved in the Health sector.

Scope of geographical eligibility for procurement and grants NA

4.4 Indicative Budget

Indicative Budget components	**EU contribution (amount in EUR)**	**Third-party contribution, in currency identified**
[**Objective 1/2/3/**To boost health security and resilience composed of	1 500 000	0
Indirect management with a pillar assessed international organisation (PAHO) - cf. section 4.3.1	1 500 000	0
Evaluation – cf. section 5.2 **Audit** – cf. section 5.3	(covered by another Decision)	N.A.
Contingencies	N.A.	N.A.
Totals	1 500 000	

4.5 Organisational Set-up and Responsibilities

A high-level Project Steering Committee (PSC) composed of: the representatives from Cofepris (Comisión Federal para la Protección Contra Riesgos Sanitarios), representatives of the Council of Ministries of Health and Central America (COMISCA), representatives of the Health Ministries and/or regulative agencies of the concerned countries, representatives from the Delegation of the European Union in Mexico and the implementing partners (PAHO Mexico)will be established to provide strategic guidance and to oversee overall project implementation. EU Member States and members of the EU – Latin America and Caribbean partnership on local manufacturing of vaccines, medicines and other health technologies, and strengthening health systems resilience may be invited as observers. PAHO Washington will also be invited as observer in order to strengthen the linkages and synergies with the regional sanitary project. Each PSC meeting will be composed by two parts, one dedicated to health strengthening and resilience in Mexico (including a session on health financing) and another dedicated to Central America. The responsibility of organising the PSC meetings will lie with the implementing partners, in complementarity with the beneficiary. The PSC will take place once a year and the first one will take place within two months from the start of the project. The first PSC will allow signing the MoUs with Central American countries in view of a successful implementation, as well as with the regulatory agencies of the EU MSs countries involved in the project implementation. This EU project is the first existing initiative to federate the EU Member States in Mexico. All EU Member States are wishing / attempting to establish a fruitful dialogue with Cofepris mainly for commercial reasons, promoting the EU pharmaceutical companies. By allowing the alignment of the Mexican regulation for medicine to the European one (as it is already officially the case) and supporting the definition of more open and clearer implementation processes for medicine distribution, the project will benefit the commercial interests of all the EU Member States. The 7 Member States who will participate in the project will be given the possibility to involve their national authorities of medicine regulation in the exchange of experience, regulation and implementation mechanisms comparison and training of the Mexican counterpart.

The Economic Commission for Latin America and the Caribbean – ECLAC will also be associated in the project, being informed about its results and – eventually - invited as an observer in the management meetings, together with representatives of the Mexican Ministry for Foreign Affairs..

A Project Operational Committee (POC) will be established to oversee the implementation of the activities, budget execution and assess performance of each contract. It will meet (virtually or in a face-to-face way depending on the evolution in the COVID-19 pandemic) every 3 months and will include internal or external sessions, according to necessity, the latter involving all government/public or private actors included in this Action. The organisation of these meetings lies with the implementing partners.

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

5 PERFORMANCE MEASUREMENT

5.1 Monitoring and Reporting

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. An operational working group will be established to monitor regularly the project implementation and lease with the Embassies of the Member States participating in the project. Civil society and the private sector, in particular European, will be regularly consulted though dedicated consultations during the project implementation to increase the monitoring of health public policies and foster partnership and dialogue in project implementation.

With regard to reporting, 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). Each report shall be complemented by a max 5-page summary that will be distributed to the engaged Member States to ensure flow of information and partnership.

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

Roles and responsibilities for data collection, analysis and monitoring:

For each contract, the implementing partner shall have the responsibility of monitoring and reporting on the progress of the implementation at the corresponding output and outcome level on a yearly basis. Detailed logical frameworks may be developed at contract level in accordance with the monitoring system of the implementing partner and with the support of the beneficiaries.

Each implementing partner will provide annual narrative and financial reports, covering all activities, accomplishments, and financial performance. Reports will provide an accurate account of implementation to date, difficulties encountered, changes introduced, as well as the degree of achievement of its results (direct outputs and outcomes) as measured by corresponding indicators, using as reference the log frame matrix and the list of result indicators. The implementing partner may propose updates to the logframe and agree with the Contracting authority new targets throughout the project and upon duly justified request.

Final consolidated narrative report, after the completion of each contract, must be provided no later than three months after the operational closure of the activities. Relevant information collected will be also shared during Project Steering Committee and Project Operational Committee meetings.

Results at outcome and impact level will be communicated by the EU to the members associated to the EU-LAC partnership above mentioned on a regular basis and will be integrated in the monitoring framework for Social Cohesion in Mexico.

5.2 Evaluation

Having regard to the nature of the Action, a final evaluation will be carried out for this action or its components through a joint mission 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 aims to leverage sustainable financing and support bankable projects.

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.

The evaluation reports will be shared with the partners and other key stakeholders following the best practice of evaluation dissemination. The implementing partner and the Commission shall analyse the conclusions and recommendations of the evaluations and, where appropriate, apply the necessary adjustments.

Evaluation services will be contracted under a framework contract.

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

5.3 Audit and Verifications

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

6 STRATEGIC COMMUNICATION AND PUBLIC DIPLOMACY

The 2021-2027 programming cycle adopted 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:

Contract level		
x	Single Contract 1	Contribution agreement with PAHO (supporting technical assistance)

[i] 8 https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1597339415327&uri=CELEX:52020DC0245

[ii] [ii] www.sanctionsmap.eu. Note that the sanctions map is an IT tool for identifying the sanctions regimes. The source of the sanctions stems from legal acts published in the Official Journal (OJ). In case of discrepancy, the OJ prevails.