

Project Sheet:

No Heparin, No Modern Medicine

Securing locally produced sodium heparin for patients in Cuba

General Objective:

To reduce patient morbidity and mortality in Cuba by strengthening local production capacity for low molecular weight sodium heparin (LMWH).

Specific objective:

Develop the capacity for mass production of low molecular weight sodium heparin in Cuba to sustainably meet demand at a lower cost than through imports.

Expected results:

1. Demonstrate the capacity for mass production of low molecular weight sodium heparin in Cuba by producing batches of 80,000 doses each of 40 mg and 60 mg during both phases.
2. Train at least 20 specialists to execute the aforementioned production.
3. Demonstrate the quality of locally mass-produced low molecular weight sodium heparin.

Potential impacts:

- The Cuban health authorities minimize imports of an essential drug like LMWH in favor of the locally produced quality product, which is 50% cheaper per dose compared to imported LMWH. This could result in potential savings of over 2.36 million euros per year, with an expected annual production of more than 1.13 million units at an estimated price of 3.92 euros per dose.
- The Cuban product, offered at a fair price, can assist more patients in the Global South.

These expected impacts—anticipated after the project—have been discussed with Cuban health and political authorities at the highest level, and there is significant interest in monitoring the results both during and at the conclusion of the project.

Duration: July to December 2024 for the first phase

January to October 2025 for the second phase

Budget: €300,000 total - €150,000 in 2024 and €150,000 in 2025

Target: This project primarily supports and benefits an estimated 100,000 patients in the Cuban health system who will have access to this essential, locally produced medicine

This project will prioritize the treatment of patients in specialized hospital services, including oncology and orthopedics, with a primary focus on the Institute of Immunology and Hematology across the western, central, and eastern provinces of the country.

It also benefits the national pharmaceutical industry, the 20 specialists managing production, various research centers of BioCubaFarma, and other public health institutions involved in authorizing the validity, manufacture,

quality control, and clinical use of this medicine. This includes the Center for State Control of Medicines, Equipment, and Medical Devices (CECMED) and the National Coordinating Center for Clinical Trials (CENCEC).

It has the potential to benefit millions of patients in southern countries by providing access to a basic drug at a fair price.

Previous phases:

1. During the peak phase of the COVID pandemic, mediCuba-Europe, in collaboration with mediCuba Switzerland, the Swiss Development Cooperation (SDC), and at the request of the Cuban health authorities, contributed 200,000 euros in August 2021 for the emergency import of sodium heparin. This funding facilitated the purchase of approximately 42,000 doses as part of a larger order managed by the Cuban partner AICA.
2. Between October and November 2021, mediCuba-Europe purchased 24,000 doses of Enoxaparin, which were sent to the Cuban Ministry of Public Health, with an estimated value of 110,000 euros.
3. Between 2022 and 2023, mediCuba-Europe supported Laboratorios Farmacéuticos AICA in Havana in acquiring the capability to manufacture injectable low molecular weight sodium heparin, investing 466,000 euros. The product was accredited by the competent Cuban authorities on August 10, 2023, with registration No. M-23-046-B01.

Therefore, this third phase represents a logical and coherent continuation of the previous two phases and aims to complete the cycle of import substitution and ensure the availability of a basic medicine for the population. The goal is to achieve mass production capacity and establish the ability to meet future national demand for this essential medical preparation.

The projected production of 80,000 doses in each phase, while only meeting 6% of the annual national demand, will demonstrate the technical feasibility and economic viability of mass production. The cost of a locally produced dose is estimated at 1.84 euros, compared to 3.92 euros for an imported dose, representing a 54% savings, or 166,400 euros per phase. This will be crucial for the health authorities in deciding to invest in local production of Cuban LMWH.

The proposed budget for producing 80,000 doses in each phase (2024 and 2025) totals 300,000 euros (150,000 euros per phase). This budget covers the import of materials (125,000 euros for 6.5 kilograms of sodium heparin raw material per phase) and for reagents, standards, and columns for quality assurance and testing (25,000 euros per phase).

AICA and mCE have identified potential suppliers from previous phases. Over the years, AICA and mCE have developed a relationship characterized by transparency, mutual respect, and solidarity, which is also reflected in this highly relevant joint project. AICA and mCE agree to coordinate the international fundraising campaign to be launched once AICA confirms that the data in this document is accurate and that the projections are realistic.

Financing:

mediCuba-Europe has invested a total of 776,000 euros in phases 1 and 2 since 2021.

For phase 1 in 2024, mediCuba-Europe has 130,000 euros but urgently needs an additional 20,000 euros to fulfill the commitment with AICA and the Cuban health system to produce the first batch of 80,000 doses by 2024.



For 2025, to produce another 80,000 doses, 150,000 euros will be required during the first half of the year.

Monitoring and reporting:

mediCuba-Europa has the experience, contacts, and capacity, with its representation in Cuba and the Secretariat in Switzerland, to oversee the project and provide donors with regular updates as well as a final report.

mediCuba-Europa, August 2024