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COFEPRIS and the Standards Alliance Sign Letter of Intent on Technologies used in Health Emergencies

- **Establishes a route for the Medical Devices Regulatory Convergence Project for COVID-19**

The Federal Commission for Protection against Health Risks (COFEPRIS) and United States parties signed a letter of intent focusing on a new cooperation project within the framework of medical technologies which seeks to encourage and facilitate mutual contacts, information exchange and training among government agencies, health institutions, specialists and industry.

On behalf of the United States, the letter was signed by the United States Agency for International Development (USAID), the American National Standards Institute (ANSI), and also the regional organization of the Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC-MTS).

With this document, the participating institutions set out a path to work on regulatory convergence focused on medical devices which will promote good regulatory practices and the referencing to internationally recognized standards. This will bring the two countries closer to the same standards, particularly in the authorization of technologies used in health emergencies such as COVID-19.

In his participation, the COFEPRIS representative, Alejandro Svarch Pérez, highlighted the commitment of the health institution to maintain a health policy able to offer access and innovative alternatives to people, always with guarantees of safety, quality and effectiveness. He explained that this can only be achieved by migrating to an international regulatory model for medical devices.



“The most important aspect of this letter [of intent] is to reiterate COFEPRIS's complete willingness to work constructively and consolidate this partnership, supporting it with technical substance”, the head of the office said.

In her first official visit to Mexico City, USAID’s Deputy Director for Latin America and the Caribbean, Mileydi Guilarte, recognized the signing as a step towards improving bilateral cooperation between countries, boosting innovation and bringing innovative alternatives to people.

Guilarte applauded the Mexican regulator’s commitment and said it was a good start to work together and see progress in the coming months.

The Executive Secretary of the IACRC-MTS, Sandra González Aguirre, highlighted Mexico’s preponderant role regarding international standards, which places the country in a privileged position with many opportunities for collaboration, but also generates a responsibility for its industries and organizations.

González Aguirre congratulated COFEPRIS on the installation of the [new Regulatory Optimization Committee with the Pan American Health Organization](#), which she assured will help Mexico to be a pioneer in terms of convergence agreements.

The instrument considers providing support for developing technical, scientific and ethical capacities to enhance industrial development and regulatory policies, allowing the learning and mastering of new technologies. It also establishes arrangements for the implementation of projects aimed at promoting the use of international standards for medical device regulatory purposes.

This collaboration is part of the technical collaboration between the two countries to promote greater harmony and openness between regulatory systems.

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