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CITELINE REGULATORY

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Latin America Sets Sights On Creating New Regional Medicines Regulator

Centralized Marketing Authorization Should Be Priority, Says Industry

by Francesca Bruce

Regulators in Mexico, Colombia and Cuba have affirmed plans to create a new Latin American and Caribbean Medicines Agency.

Mexico, Colombia and Cuba, are moving ahead with plans to create a new Latin American and Caribbean Medicines Agency that would work towards regulatory convergence as a means of improving access to medicines and stimulating innovation, said regulators from the three countries. The pharmaceutical industry is in support of a new agency and says it would like to see a new regional body follow in the model of the European Medicines Agency.

Cofepris, Invima and Cecmed, the respective regulatory agencies from Mexico, Colombia and Cuba, made the announcement in a recent statement following a meeting between the directors of the three bodies. The aim of the regulator is to help the region become more self-sufficient in terms of health care and to support the authorization process for medicines and vaccines in health emergencies, said the statement.

The proposal to establish a new agency was tabled by Mexican representatives in January at a summit of the Heads of State and Government of the Community of Latin American and Caribbean States. At this meeting Cofepris head Alejandro Ernesto Svarch Pérez outlined short- and long-term ambitions for the new regulator to:

- achieve regulatory convergence and mutual recognition of authorizations to guarantee effective access to health products and supplies,
- stimulate and enable R&D of innovative products and provide regulatory certainty throughout the region,

- support local production and integration of local supply chains,

- explore public procurement mechanisms for medicines to guarantee access and sustainable financing. These would prioritize "self-sufficiency," such as contracts with regional manufacturers.

The new agency would also aim to develop health regulatory professionals through education and information exchange programs.

It is not yet clear when the new agency would be set up. Countries as well as Mexico, Colombia and Cuba that have so far expressed interest in taking part in the project include Bolivia, Dominica, Ecuador, El Salvador, Honduras, Jamaica, and the Dominican Republic.

Desirable?

A regulatory agency for Latin America and the Caribbean would be "desirable and necessary" if it is designed to strengthen regulatory systems and pursue harmonization and convergence of regulatory frameworks in the region and align them with international regulations, Fifarma, the Latin American Federation of the Pharmaceutical Industry, told the *Pink Sheet*.

It added that the pharmaceutical industry could benefit from increased harmonization, but that the main advantages would be for patients who could access innovative medicines more quickly if a centralized authorization process is considered.

Harmonized regulations across the region could reduce regulatory burden on companies and make it easier to bring products to market, said Pharmalex, which provides consultancy services to the pharmaceutical and biotech industry. Companies could also benefit if the regulator standardizes requirements for clinical trials, labeling and packaging as well as post-marketing surveillance standards, it told the *Pink Sheet*.

"Clear and transparent" regulatory pathways for new therapies also help stimulate innovation in the region, Pharmalex added.

European Model?

There is little information about how the new agency will achieve its goals and it is unclear what model it will follow. However, one that follows that of the European Medicines Agency could increase the standards of some national agencies, said Fifarma. "From our experience in Latin America and the Caribbean, this is the most desirable approach to increasing the regulatory level in the region," it said. Pharmalex pointed out that some Latin American markets already consider EMA regulations as a reference for implementing guidelines and standards.

One of the areas the new regulator should prioritize is a centralized marketing authorization process that reduces the timelines for granting access to innovative medicines, Fifarma said. Companies can access such a system in the EU. With a centralized authorization evaluated by the EMA, a company can secure authorization in all EU member states.

In terms of other duties, Fifarma would like to see the regulator prioritize improving work-sharing between regulators, and improved pharmacovigilance and patient safety activities.

Caution

Pharmalex, however, warned that there was also the possibility that a regional regulator could "become overly bureaucratic" and stifle innovation if it imposed "excessively burdensome requirements for drug developers." The risk to companies is that they would have to "navigate an additional layer of regulation," it said. This could lead to an increased burden as companies comply with national and regional regulations.

Compliance with regional regulations could mean added costs and resources for companies, including hiring new staff to manage regulatory processes and conduct additional tests, it commented.

Fifarma warned that it may also be challenging to get the new agency off the ground and ensure that all regional authorities were on board. It could be difficult for them to reach a "consensus about the key elements for the constitution of a regional agency, for example, the legal basis, the status of independence and sovereignty of the national authorities, the essential activities to be handled, financing and economic resources and the drafting of regional sanitary regulation and guidelines," it said.

Fifarma pointed out that Brazil had so far rejected the idea of joining the initiative and that any moves by Brazil to strengthen its regulatory environment would be conducted through the Pan American Health Organization (PAHO).

The pharmaceutical industry has offered technical support to authorities in Mexico and Colombia with regard to setting up the new agency, but it has not yet been invited to contribute to the initiative, said Fifarma.

Pharmalex believes industry should be "deeply involved" in any discussions on creating a new regulator in the region. However, it added that industry participation must be balanced with "the interests of other stakeholders," including governments, health care professionals and patients.

Although industry has "valuable expertise and knowledge" of drug development, manufacturing and distribution, it also has "a commercial interest in the regulation of pharmaceutical products, and it is important to ensure that their involvement does not undermine public health and safety

or compromise the independence of the regulatory authority."

The Status Quo

Latin American markets currently have their own regulatory health authorities, in some there is a dedicated agency, while in others the health ministry takes responsibility for duties including drug approval or post-marketing surveillance.

PAHO also gives technical support and cooperation to these authorities. It also promotes regional cooperation and harmonization, said Pharmalex.

Regional efforts to strengthen regulatory cooperation and harmonization have been made, for example through the Southern Common Market (MERCOSUR) and the Andean Community. "These organizations have established mechanisms for harmonizing regulatory requirements and procedures for medicines. However, no relevant benefits have been implemented in terms of regulatory harmonization and each country involved with the initiative continues to have their own requirements," said Pharmalex.

Pharmalex also highlighted the Central American Technical Regulation (RTCA), which is a set of technical standards that apply to products, services, and processes in some Central American countries (Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama). This regulation aims to guarantee the safety, quality, and efficacy of products and services in the region and promote trade and economic development by harmonizing technical regulations among member countries, it said.