# REGULATORY LANDSCAPE IN MEXICO'S HEALTHCARE SECTOR

INFINITUS
INTERNATIONAL MARKET DEVELOPMENT

## Modification to the Health Supplies Regulation

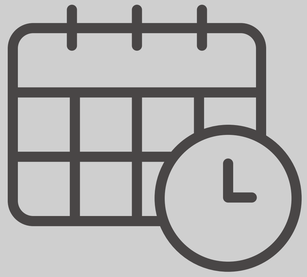
The presidential decree modifying the Regulations for Health Supplies (RIS, in Spanish) aims to streamline administrative processes, eliminate bureaucratic redundancy, optimize health registration extensions, strengthen health surveillance, and promote innovation in health supplies. This is intended to result in a more efficient regulation aligned with international standards.

## The positive impact

The positive impact of this decree on the healthcare sector is anticipated to enhance the quality, safety, and efficiency of health supplies by prioritizing their continuous review and monitoring throughout their market lifespan.

## Reducing processing times

The measures also aim to reduce processing times and costs by accepting documents in English and eliminating unnecessary requirements. They also seek to facilitate access and availability of health supplies by streamlining the renewal of sanitary registrations, ultimately preventing cyclical shortages.



## Internationally recognized

Acknowledging COFEPRIS's efforts, the National Chamber of the Pharmaceutical Industry (CANIFARMA, in Spanish) supports measures ensuring quality, safety, and efficiency throughout the lifecycle of health supplies. CANIFARMA also recognizes COFEPRIS's role as an internationally recognized regulatory authority and its commitment to updating and simplifying the regulatory framework to promote innovation and competitiveness in the sector.

## Some key points of this decree include:

- The Federal Commission for Protection against Health Risks (COFEPRIS, in Spanish) accepts English-language documentation for Health Authorization without translation, requiring authentication and legalization of documents from other countries' authorities.
- Products labeled for the public sector must be distinguishable from those in the private sector.
- The Biotechnological Products Evaluation Subcommittee is removed from the approval process for biocomparable biotechnological drugs, with the New Molecules Committee's opinion deemed sufficient.
- Clinical studies from the country of origin may serve as evidence to initiate the registration process for biocomparable biotechnological drugs. However, when seeking the extension of Sanitary Registration, clinical studies conducted in Mexico must be provided.
- The first extension request is due five years after registration and should be resolved within 120 days.
- To secure the initial Sanitary Registration extension, regulatory authorities will monitor all inputs, considering their performance during the initial market years.