



The Guide to Life Sciences: Key issues for senior life sciences executives

2025

**Mexico: transforming healthcare
through ambitious reforms and
regulatory changes**

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The fifth edition of the *Guide to Life Sciences* delivers key analysis designed to help senior life sciences executives better understand the strategic and legal IP challenges that they face around the world. This specialist intelligence will help them to protect, enforce and monetise the IP rights that are so crucial to businesses in the space.

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Mexico: transforming healthcare through ambitious reforms and regulatory changes

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INTRODUCTION

The healthcare system in Mexico has become one of the most critical issues on Mexico's political agenda. In recent years, the sector has undergone significant regulatory changes, with new rules and proposals shaping policy across a wide range of areas, which involve access to medicine and regulatory approvals to innovation and intellectual property.

The following sections briefly describe some of the most relevant proposals and regulatory modifications already in place, offering examples from different perspectives of the healthcare sector and illustrating the scope of ongoing changes.

NEW MODELS OF ACQUISITION

The year started with a new model of public acquisition of health products. The supply of health products has become an urgent and fundamental need within the public healthcare sector, where the lack of these supplies shows severe repercussions that directly affect the exercise of the human right to health for the Mexican population.

For the above, and to ensure the supply of health products in public healthcare institutions, the President of Mexico, Claudia Sheinbaum, announced a New Consolidated Model for the Procurement of Health products and Medical Supplies for the 2025–2026 period on 31 October 2024. This initiative would be led by the Ministry of Health and the Laboratories of Biologics and Reagents of Mexico, SA de CV (BIRMEX).

The new model involved an investment of 130 billion pesos, therefore it was described as one of the most ambitious public procurement procedures in the country's history. It included both generic and patented health products. With the inclusion of both national and international suppliers, and the addition of 4,454 drug and medical supply codes, with volumes estimated at 4.934 billion units, calculated to meet the needs for the next two years, this framework aims to ensure the availability of health products within the National Health System for Well-being.

Initially, it was stated that the tender call would be published on 2 December 2024, with the award decision to be made on 17 December of the same month. Due to changes in its format, the new date was set for 10 December, with the award decision scheduled for 26 December. However, the tender was eventually published on 13 December and the award decision was scheduled for 4 January. This date was once again rescheduled to 13 January 2025, but the award decision did not take place until 17 January 2025.

The results of the tender were surprising, as the award decisions under the Consolidated Model for the Procurement of Health Products and Medical Supplies for 2025–2026 were revoked by April 2025, allegedly due to corruption in the process. Therefore, it was necessary to implement urgent measures to acquire health products in the public sector. Moreover, all parties involved should continue working on suitable strategies to ultimately adjust to these new models of acquisition of health products aiming to ensure legal certainty and the proper observance of exclusive rights.

IMPORTATION OF HEALTH PRODUCTS WITHOUT A MARKETING AUTHORISATION

In parallel with the consolidated procurement, on 4 December 2024, the 'Decree to Obtain the Import Permit for Health Supplies Intended to Ensure the Supply of the Public Sector' was published in the Federal Official Gazette. This decree allows the importation of health

supplies into Mexico that have a sanitary authorisation issued by regulatory authorities in specific countries listed in the decree, aimed at supporting the consolidated procurement by BIRMEX and the Ministry of Health.

As this decree could provide some benefits to the public healthcare system, it is worth mentioning that the industry has shown some concern as it contains some loopholes that may result in unfortunate application or oversight of the applicable legislation in force. In other words, this new decree was welcomed by some participants but has been carefully analysed by others as well as rejected. The main concern lies in matters of safety, efficacy and quality of the products primarily, as well as the risk of ignoring previous rights granted (marketing authorisations, patents, etc.), and granting an unjustified competitive advantage to foreign entities in violation of the applicable legislation. Also, there were doubts regarding the role that would be played by this decree within the public tender.

NEW PATENT LINKAGE

On 6 March 2025, a decree providing guidelines about the technical collaboration between the Mexican Institute of Industrial Property (IMPI) and the Federal Commission for Protection against Health Risks (COFEPRIS) was published in the Federal Official Gazette.

The most relevant provisions included within the decree are the publication of the list of marketing authorisation (MA) applications and the 'opportunity' to file an opposition by the patent owner if they consider that a patent right is affected by the MA applications.

The decree is legally grounded on certain provisions of IP law, health regulations and the USMCA. It seems that the decree intends to comply with the provisions of the USMCA, where it is provided that if a person or company (patent owner) is directly affected by a proceeding (in this case the MA applications), they must be given a reasonable opportunity to present facts and arguments, prior to issuing the corresponding decision on the MA application.

However, the USMCA establishes that it is the responsibility of the state party to provide corresponding notice to the patent holder who would be directly affected by the marketing authorisation application proceeding. On the contrary, this decree imposes on patent holders the burden of identifying themselves as affected parties without being personally notified by COFEPRIS or IMPI.

In addition, it seems that the opposition opportunity will take place before COFEPRIS and not IMPI, even though IMPI is the patent office (ie, the authority that handles the information related to the owner or its licensee or sublicensee, namely, those who could be directly impacted by the patent linkage mechanism).

The guidelines provided are a step forward in the Mexican Linkage System, as they clarify some of the information to be exchanged by these authorities. Nonetheless, the decree does not observe the obligations of proper notice established in the USMCA for Mexican Patent Linkage. This conclusion can be summarised as follows: the legal burden, obligations and formalities of a notice process differ from those of an opposition system.

The decree entered into force on 3 June 2025, 60 working days after its publication. Thus, the proceedings described in the decree are currently being used and tested, with a practical impact and results on whether the decree provides patent holders with the opportunity to oppose. It is still to be established if they are enough to prevent patent infringement.

CONSTITUTIONAL REFORM INITIATIVE REGARDING PHARMACEUTICAL SOVEREIGNTY AND SAFETY

On 22 April 2025, a proposal was submitted to the Deputies Chamber proposing to reform articles 4, 25 and 28 of the Mexican Constitution, regarding pharmaceutical sovereignty and security.

The proposal calls for modifying the legal framework at the constitutional level, requiring the state to guarantee pharmaceutical sovereignty and security. This change is intended to enable the subsequent adaptation of secondary laws, programmes and budgets with a long-term vision.

If approved, this initiative would undoubtedly have an impact on Mexican health legislation and, of course, would require modification of processes for the evaluation and approval of health products, as well as authorisation of activities in establishments focused on the production, manufacture, storage and distribution of health products.

In other words, this proposal would lead to drastic changes in the current system for producing health products. If these changes are not harmonised with applicable legislation and international treaties, and coordinated with the institutions, entities and stakeholders involved in health processes, they could hinder proper access to health products, to the detriment of patients.

NEW DECREE TO ACCELERATE IMPORTATION OF HEALTH PRODUCTS THROUGH THE PAN AMERICAN HEALTH ORGANIZATION

On 11 June 2025, the following was published in the Official Gazette of the Federation:

DECREE recognizing as equivalent the requirements established in the Health Regulation and the technical evaluation procedures carried out by the Federal Commission for the Protection against Sanitary Risks for the granting of the marketing authorization of health products, to the requirements, tests and evaluation procedures carried out by the regulatory authorities of reference to allow the sale, distribution and use of health products in their country, and to the evaluations of the World Health Organization's Prequalification Program, as well as the criteria for the importation of products for the treatment of emerging, unattended diseases or in cases of national emergency.

The Decree establishes the criteria for the importation of products for the treatment of emerging and unattended diseases or in situations of national emergency. Among its provisions, it highlights that certain products such as vaccines, medicines and medical devices may be acquired by the Ministry of Health through the Strategic Fund and the Revolving Fund of the Pan American Health Organization (PAHO), without the need for marketing authorisation in Mexico.

NEW ABBREVIATED REGULATORY PATHWAY: RELIANCE

On 28 August 2025, a decree came into force issuing general guidelines for applying the abbreviated regulatory route to grant marketing authorisations for health products. These guidelines incorporate requirements, tests and evaluation procedures established by reference regulatory authorities (RRAs) and the World Health Organization's prequalification programme, which were published on 18 July in the Official Gazette of the Federation.

The decree establishes provisions that COFEPRIS must observe in line with the Good Regulatory Practices recommended by the WHO. These provisions recognise

the decisions of other reference regulatory authorities and the WHO Prequalification Program for Medicines in granting marketing authorisations for health products, including medicines classified as new molecules, generics, innovative biotechnology, biocomparable biotechnology, biological products and vaccines, as well as medical devices in Mexican territory. The aim is to optimise resources and increase efficiency to ensure broad, safe and timely access to these products with guaranteed safety, quality, efficacy and performance.

PROPOSED REFORM TO THE MEXICAN INDUSTRIAL PROPERTY LAW

In September 2025, a draft decree was published proposing amendments to the Federal Law for the Protection of Industrial Property (LFPPI).

Among the proposed amendments, a key change is the modification of the second paragraph of article 162 of the IP Law, concerning the patent linkage system, by eliminating the reference or cross-reference to article 167 bis of the Health Supplies Regulation.

This suppression may appear minimal but it carries significant implications. It is based on a matter of legislative technique, as the regulation in question has been superseded by the new legislative framework on industrial property. A regulatory provision derived from a repealed law should not take precedence over what is established in a new federal law. In other words, the reform aligns with the principle of normative hierarchy and ensures consistency with the current legal framework.

However, this seemingly minor reform, namely, the elimination of the remaining provisions of the regulation corresponding to a repealed law, has significant implications.

The suppression of the remand to the regulatory provision implies that the legal doctrines and case laws that broadened the preventive scope of the linkage system, based on article 167 bis of the Health Law Regulations, will no longer be applicable. It is important to recall that the broad legal interpretations allowing the publication of formulation and use patents were based on the interpretation of the article that has now been removed from the current law.

As article 167 bis of the Health Supplies Regulations is no longer applicable, the new guidelines governing the linkage system, published by decree in the Federal Official Gazette on 6 March 2025, and in force since June of the same year, described above, are now the relevant legal instrument.

As noted in the communication issued at the time of their publication, these guidelines fail to comply with the obligations assumed by the Mexican state under the USMCA, particularly with respect to the requirement of formal notice and a reasonable opportunity to oppose, which has been unduly limited to a period of only 10 business days.

In the absence of an adequate mechanism for direct notification, the burden is shifted to the patent holder, who must independently attempt to identify any potential infringement of their patent rights, with very limited or minimal information.

Moreover, if patent rights are adversely affected, it may be necessary to challenge the constitutionality and incompatibility of these guidelines with the obligations established under both the USMCA and the applicable domestic legal framework.

Among other aspects, the proposal also introduces one provision concerning patent term extensions (PTEs) to compensate for delays in obtaining regulatory approval for a pharmaceutical product.

Under the draft, COFEPRIS would notify IMPI of any regulatory delay and the corresponding compensatory period. IMPI would then inform the patent holder, who would be responsible for covering the issuance fees for the compensatory certificate.

In short, while the draft provision seems designed to comply with article 20.46 of the USMCA, it does so only partially, focusing mainly on IMPI's obligations. At this point, no proposal, law, or regulation has been issued or published regarding COFEPRIS's role in defining unreasonable delay and determining compensation.

Accordingly, the mechanism remains incomplete at this stage, and it will be necessary to await the publication of corresponding regulations establishing the legal framework for the process before COFEPRIS can request or decide on PTEs. These regulations should establish clear rules and guidelines to define what constitutes an unreasonable delay, since approval times vary depending on the type of product and the proceedings before the regulatory agency. Needless to say, the parameters for compensating the patent term due to such delays are also essential.

While the proposal acknowledges the importance of PTEs, it falls short of providing a comprehensive, predictable and solid legal framework for the entire process. In brief, we must wait for regulations that will establish the process and rules for COFEPRIS to govern PTEs related to unreasonable delays.

CONCLUSION

Mexico's healthcare system has become one of the most pressing issues on the country's agenda. The proposals and regulatory modifications outlined in this article illustrate just a few examples from different angles of the health sector, but many other regulations and guidelines have already been implemented, and additional initiatives are underway.

Together, these measures reflect an ongoing attempt by the government to redefine priorities, strengthen institutions and respond to growing public demand for better healthcare outcomes.

It is clear that the health system continues to face significant challenges; however, the reforms already enacted, as well as the proposals currently under discussion, offer important areas of opportunity.

If implemented with balance and consistency, all these reforms could eventually contribute to building a system where access and innovation are not competing objectives but complementary pillars. Achieving this equilibrium will be critical for Mexico's ability to deliver a healthcare model that is sustainable, equitable and aligned with international best practices.



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