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

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The sixth 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.

Mexico: assessing the impact of the reshaped IP and regulatory framework

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Summary

INTRODUCTION

Mexico's pharmaceutical and life sciences regulatory landscape has undergone significant developments throughout 2026, marking one of the most substantial regulatory shifts in recent years for the innovative sector.

Recent amendments to the Federal Law for the Protection of Industrial Property and to the Health Law Regulations have introduced important changes in areas such as patent-term compensation for regulatory delays, regulatory data protection and patent linkage, while also refining several general regulatory and procedural provisions applicable to the authorisation and commercialisation of pharmaceutical products and medical devices.

These reforms reflect Mexico's continuing efforts to modernise its IP and regulatory framework and align domestic legislation more closely with its international obligations, particularly those arising under the USMCA. In particular, the amendments seek to address longstanding discussions concerning effective protection for pharmaceutical innovation, regulatory transparency and the interaction between sanitary authorities and IP rights.

At the same time, the reforms raise several crucial interpretative and practical questions regarding their scope, implementation and enforcement. Several provisions remain broadly drafted and will likely require further clarification through secondary regulations, administrative practice and judicial interpretation. Issues such as the calculation and enforceability of patent-term compensation, the scope and mechanism of regulatory data protection, the practical operation of the patent linkage system and the treatment of ongoing or previously initiated procedures are expected to become key topics of discussion and potential litigation in the coming years.

Against this background, this chapter highlights the most relevant amendments and provides a preliminary assessment of their potential impact on innovative pharmaceutical companies operating in Mexico, as well as the strategic considerations that may arise in connection with market exclusivity, lifecycle management and regulatory enforcement.

IMPACT OF REFORMS TO THE MEXICAN INDUSTRIAL PROPERTY LAW ON THE PHARMACEUTICAL SECTOR

On 3 April 2026, amendments to the Federal Law for the Protection of Industrial Property (LFPPI) were published in the Official Gazette of the Federation, entering into force on 4 April 2026.

In general terms, the amendments introduce measures aimed at streamlining and improving the efficiency of various procedures set forth in the law. At the same time, they strengthen legal certainty for holders of patents, registrations and other protected exclusive rights.

Among other aspects, these amendments included a new and key provision related to patent-term compensation certificates arising from delays in the regulatory approval of pharmaceutical products.

Under the reform, the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) would notify the Mexican Institute of Industrial Property (IMPI) of any regulatory delay, as well as the corresponding compensatory period. IMPI would then inform the patent holder, which would be responsible for covering the costs associated with the issuance of the compensatory certificate.

This new provision seeks to comply with article 20.46 of the USMCA, however it only addresses IMPI's obligations. At first glance, the inclusion of such a provision constituted a partial or incomplete implementation of the referenced USMCA provision.

At that stage, further amendments to the Health Law or its Regulations were still required to complete the new mechanism. In our view, absent such additional provisions, it could not be concluded that Mexico was fully compliant with its USMCA obligations regarding patent-term compensation for regulatory delays.

Until then, there was no legal or regulatory framework establishing the criteria for determining whether a regulatory delay had occurred or how the corresponding patent term compensation would be granted.

Accordingly, it was necessary to await the issuance of implementing regulations establishing clear rules and guidelines to define what constitutes an "unreasonable delay", taking into account the various types of products subject to regulatory approval before the health authority, as well as the rules, parameters or formulas for determining the appropriate patent-term compensation.

This decree of course included some transitory provisions of the amendments. The most relevant established that ongoing proceedings shall be resolved in accordance with the legal framework in force at the time they were initiated.

In that sense, an initial interpretation could suggest that the reforms apply only to patents that were filed, prosecuted and granted after the entry into force of the amendments (ie, 4 April 2026).

However, the interpretation on the timeliness of applicability is much more complex than it seems. Beyond a literal interpretation, cases could be assessed under a case-by-case approach, also taking into account the potential interpretation of the provisions of the USMCA based on the corresponding hierarchy of the international treaties in accordance with the Mexican legal system. And let's not forget the entering into force of the Health Law Regulations updates that would also impact the mechanism.

After some days of uncertainty on the next steps, on 24 April 2026, a Decree amending the Health Law Regulations (***Reglamento de Insumos para la Salud***) was published in the Official Gazette, addressing not only patent-term compensation for regulatory delays but also regulatory data protection and some minor additions to the patent linkage provisions.

RELEVANT AMENDMENTS IN THE REGULATORY FIELD

As mentioned, the IP Law amendments were "incomplete" without the corresponding update of the Health Law Regulations. These amendments were expected to include clear rules and guidelines to define what constitutes an "unreasonable delay," taking into account the different types of products subject to regulatory approval procedures before the health authority, as well as the rules, parameters, or formulas to determine the appropriate patent term compensation.

It is worth mentioning that, without such framework, it could not be concluded that Mexico was fully complying with its USMCA obligations regarding patent term compensation for regulatory delays.

PATENT-TERM COMPENSATION

The expected provisions after the amendments of the IP Law are finally here. The Decree amending the Health Law Regulations incorporates some provisions that were missing to "complete" the mechanism to compensate patent term for regulatory delays in the granting of marketing authorisations (MA), introduced in the recent amendments to the IP law.

The mechanism related to patent-term extensions (PTEs) in connection with delays in the MA process for new pharmaceutical products was originally contemplated under article 20.46 of the USMCA, but it included a transitional period of 4.5 years, which concluded in January 2025.

In Mexico, this mechanism was first incorporated into domestic legislation through the 3 April 2026 amendment to the LFPPI, which introduced article 136bis.

Now, in addition to the IP law, the Health Law Regulations state that compensation may be available where unreasonable delays attributable to the sanitary authority occur during the review of an MA application for allopathic medicines, provided that such delay affects the effective exploitation of a patent identified at the time the MA application was filed.

Any adjustment would be implemented through a complementary certificate issued by IMPI and may not exceed five years. The regulations also clarify that only one patent per MA procedure may benefit from compensation.

The request must be filed within 60 business days following the grant of the MA and may apply to only one patent associated with the product, as long as the patent is declared within the MA application. COFEPRIS, the Mexican regulatory agency, decides over the compensation and must inform IMPI to eventually grant the corresponding certificate.

The regulations further provide a single five-working-day opportunity to correct deficiencies or omissions in the request; otherwise, the application will be dismissed.

In addition, the amendments identify several circumstances in which compensation would not be available, including cases where:

- the patent had already been associated with a previously approved product;
- the patent was not properly identified in the original MA application; or
- the medicine had been commercialised prior to obtaining regulatory approval.

The regulations also clarify that certain periods will not be considered compensable delays, particularly where the delay derives from actions attributable to the applicant, unsuccessful administrative or judicial challenges, or force majeure or unforeseeable events.

Finally, based on the current wording it seems that the sanitary authority would be responsible for determining whether there was a delay and eventually whether compensation applies and notifying both the MA holder and IMPI of its determination. If the decision is favourable, IMPI will issue the corresponding complementary certificate in accordance with the applicable legal framework.

There are still some grey areas that were not reached by any of the new provisions within the IP Law nor the Health Law regulations. While both bodies of legislation formally introduce the possibility of patent extension for regulatory delays, they leave key aspects on the side, particularly the criteria for determining compensable delays, largely undefined.

Although the regulations provide certain parameters regarding what may constitute a reasonable delay, they do not establish how the compensation period should be assessed or determined by COFEPRIS. Moreover, it is worth considering that COFEPRIS is not an authority with expertise in the patent field, nor is IMPI in the regulatory area, thus it would be very interesting to see how they will interpret these new rules and their particularities.

The amendments on the Health Law Regulations entered into force on 25 April 2026. Ongoing procedures will continue to be governed by the provisions in force at the time of filing, and the Ministry of Health is expected to issue additional regulations to support the implementation of these amendments within 180 days. Until then, previous provisions will apply insofar as they do not conflict with the Decree.

REGULATORY DATA PROTECTION

For the first time since the North American Free Trade Agreement, which entered into force in 1994, some provisions have been issued related to regulatory data protection in the Health Law Regulations.

Under these provisions, data submitted to prove safety and efficacy of the MA of an allopathic medicine will be protected for a period of five years. During this period, generic applications and related interchangeability test reports, may only rely in whole or in part on such safety and efficacy information if the third party holds the express written consent of the MA holder, regardless of whether the information originates from an MA granted in Mexico or abroad.

Now, the Health Law Regulations state that COFEPRIS, the Mexican sanitary agency, will inform the MA holder that the submitted information may not be relied upon by third parties during the applicable protection period.

It seems that in accordance with the current Mexican framework, regulatory data protection is not subject to a formal application or standalone request procedure. Instead, protection arises automatically upon the grant and notification of the MA, therefore it looks like COFEPRIS will also inform of the protection as soon as they serve notice of the granting of the MA.

However, it is worth mentioning that these new provisions do not clarify the exact scope of the protection (ie, whether it constitutes regulatory data and/or market exclusivity).

Moreover, generic companies may simply declare whether they are relying on the clinical data submitted by the innovator, which could undermine the effectiveness of the protection since the performance of interchangeability tests already implies an indirect reliance on, or support from, the innovator's data. In addition, the amendments do not establish how such protection will be disclosed to third parties, nor do they provide clear mechanisms for its enforcement.

Prior to these amendments, there was no specific regulation for regulatory data protection or data protection exclusivity in Mexico.

However, based on the interpretation of international, along with some general provisions within the domestic legislations, it was possible to obtain regulatory data exclusivity through litigation.

Pursuant to the transitional provisions of the April 2026 amendments, the new data protection framework will apply only to MAs that are requested and granted after the amendments entered into force.

Accordingly, for MAs that were granted prior to the amendments, it may be necessary to request recognition of the protection and, if required, pursue litigation to secure it. With respect to applications that were already pending when the amendments took effect and will now be decided under the new provisions, it is still unclear whether COFEPRIS will recognise the protection automatically or whether litigation will continue to be necessary.

In addition, other complexities evolve from the current wording of the MA, particularly the mention of "allopathic medicines" and the reference to the "new molecule definition", which do not clearly allow for certainty of how this provision would be applicable to new indications and biologics, or how the temporality of the protection will apply since a wider period of protection has been granted to this type of development and, of course, how it will apply to orphan drugs, which due to the lack of a legal framework rely on the generalities of the allopathic medicines.

PATENT LINKAGE

Patent linkage is one area that gained greater attention and focus during the past year. In June 2025 the rules outlined in the Decree – which provide guidelines concerning the technical collaboration between IMPI and COFEPRIS – entered into force.

Among these new rules, the most relevant provision stated that COFEPRIS would publish a list of MA applications (generics and biosimilars) that would trigger the possibility to file an opposition by a patent owner or licensee that considers its patent rights affected by an application within 10 working days of the list's publication.

The Decree indicates that any opposition filed by the patent owner or licensee should be attached to the intergovernmental consultation that COFEPRIS must submit to IMPI, requesting its technical support to assess the product against the patents listed in the linkage gazette.

However, it is worth noting that the information disclosed in the list of generic and biosimilar applications is quite limited. Moreover, once the patent holder or licensee files the opposition form, it is no longer involved in IMPI's response or any subsequent stage of the MA application, which leaves the mechanism subject to a degree of uncertainty.

At some point, it was expected that these amendments to the Health Law Regulations would provide clearer guidelines and complement the 2025 amendments, but the changes were largely limited to technical updates, such as the removal of references to the former IP Law regulations and now it aligns to the IP Law on force, and the core framework remains unchanged.

Specifically, applicants are still required to demonstrate ownership or licensing of relevant patents recorded before IMPI with respect to active ingredients. For generic and biosimilar applications, the authority will continue to coordinate with COFEPRIS and IMPI to assess potential patent violations within the established timelines. There was no inclusion of the opposition mechanism within these amendments.

This was a great opportunity to strengthen Mexico's patent linkage system. Further, this was a key opportunity to include the obligation of due notice to the patent holder acquired by the government through the USMCA.

GENERAL REGULATORY AMENDMENTS

The Decree further includes updates to the definition and regulatory treatment of new molecules, as well as adjustments to the approval pathway for biotechnological products and biosimilars, including requirements related to technical evaluation and supporting information.

KEY TAKEAWAYS AND THE ROAD AHEAD

The recent amendments to Mexico's IP and health regulatory framework indeed represent a significant step toward modernising the legal treatment of pharmaceutical innovation in the country.

In particular, the incorporation of provisions concerning patent-term compensation for regulatory delays and data protection reflects a broader effort to align the Mexican system more closely with its international commitments and provide greater legal certainty and incentives for innovators operating in the pharmaceutical and biotechnology sectors. These developments may also contribute to strengthening Mexico's position as a more predictable and innovation-friendly jurisdiction within the region.

Nevertheless, the new framework still leaves several crucial issues unresolved. Some of the newly introduced provisions remain broadly drafted and will require further regulatory development, consistent administrative criteria and, in certain cases, judicial interpretation before their full scope, application and practical implications can be clearly determined.

This is particularly relevant when it comes to the standards and methodology for assessing "regulatory delays" and calculating patent-term compensation, the nature and effective enforceability of regulatory data protection and the level of legal certainty that the system will provide to all stakeholders, including innovators, generic companies and biosimilar applicants.

Similar concerns arise in connection with the practical operation of the patent linkage system, especially regarding the recently introduced opposition mechanism, the scope of participation available to patent holders and the continuing absence of an effective and timely notice system concerning generic or biosimilar applications that may potentially affect patent rights.

Likewise, key questions remain regarding the interaction between COFEPRIS and IMPI, the transparency of intergovernmental communications and decision-making processes and the procedural avenues available to challenge or enforce determinations related to exclusivity rights. As has historically occurred in Mexico's pharmaceutical sector, administrative practice and strategic litigation will likely play a decisive role in shaping the practical contours of these reforms.

Accordingly, while these amendments constitute positive and long-awaited developments, their ultimate significance will depend largely on how they are implemented by the authorities and interpreted in practice over the coming years.

For companies operating within Mexico's life sciences sector, close monitoring of forthcoming secondary regulations, administrative criteria and judicial precedents, particularly those adopted by COFEPRIS and IMPI, will be essential to assess risks, identify opportunities and develop appropriate regulatory, exclusivity and enforcement strategies.

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