

Amendment to the Health Supplies Regulations

Mexico City, May 6, 2026

On April 24, 2026, the "Decree amending and adding various provisions to the Health Supplies Regulations" (the "Decree") was published in the Federal Official Gazette, introducing significant changes regarding patent compensation for delays in the issuance of marketing authorizations, regulatory data protection, and the technical meeting with the New Molecules Committee.

1. Patent compensation is provided for patents protecting a medicine when unreasonable delays, attributable to the Federal Commission for the Protection against Health Risks ("COFEPRIS") in the process of granting the health registration, affect the enjoyment of the patent's exclusivity, calculated from the date of submission of the application for the marketing authorization.

The term of one of the drug's patents may be compensated by means of a supplementary certificate issued by the Mexican Institute of Industrial Property ("IMPI"), which may not exceed five years.

The application for compensation must be submitted by the holder of the marketing authorization within 60 working days of the notification of the marketing authorization and must comply with the requirements set out in the Decree.

The application for compensation shall be deemed inadmissible when (i) the patent covers a medicine that has previously obtained a marketing authorization, (ii) the patent has been included in an application for a medicine that has already obtained a marketing authorization, (iii) the patent number has been omitted from the marketing authorization application, or (iv) the medicine has been marketed prior to obtaining the marketing authorization.

For the calculation of the compensation, the following shall be considered reasonable delays: (i) delays attributable to the applicant, (ii) those arising from administrative or



judicial challenges that are not resolved in favor of the applicant, and (iii) those caused by force majeure or unforeseeable circumstances.

Once the entitlement to compensation has been determined, COFEPRIS shall inform the IMPI, which shall issue the supplementary certificate in accordance with the applicable provisions on industrial property.

2. The definition of "New Molecule" is amended to read as follows: *a pharmaceutical ingredient, biopharmaceutical ingredient, or substance with therapeutic, preventive, or rehabilitative activity, either alone or in combination, contained in a medicine or biological product that does not hold a marketing authorization within the national territory.*

This amendment is significant, as it removes the reference to new therapeutic indications.

3. Regarding *regulatory data protection*, a final paragraph is added to Article 167 Bis, which provides for the protection of technical and scientific information concerning safety, quality, and efficacy submitted to obtain a marketing authorization. Such information shall be subject to protection for a period of five years from the date of notification of the marketing authorization. This protection extends to information submitted based wholly or partly on a marketing authorization granted abroad. Furthermore, the Decree imposes an obligation on COFEPRIS not to disclose such information to third parties.
4. The technical meeting with the New Molecules Committee is replaced by a technical opinion, and for applications that have prior authorization issued by a foreign regulatory authority recognized by the Ministry of Health, such technical opinion shall be issued only if a risk associated with the medicine is identified.
5. The duration of extensions of marketing authorizations for medicines and medical devices is amended so that all extensions (first, second, and subsequent) shall be for a period of 10 years.

The Decree came into force on April 25, 2026. All matters pending at the time of the Decree's entry into force shall be governed and processed until their conclusion in accordance with the provisions in force at the time of their submission.

Furthermore, the Decree grants the Ministry of Health a period of 180 calendar days to make the necessary regulatory and administrative adjustments for the implementation of the Decree.

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