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MEXICAN LEGAL NEWS

Amendment to the Regulations for Health Supplies

On April 24, 2026, an amendment to the **Regulations for Health Supplies** was published in the Official Gazette of the Federation, which entered into force on the day following its publication.

This amendment introduces structural changes to the sanitary registration regime and strengthens various mechanisms for the protection of intellectual property and pharmaceutical innovation. The main points are highlighted below:

1. "New Molecule" is redefined as any drug, biopharmaceutical, or substance with therapeutic, preventive, or rehabilitative activity that does not hold a sanitary registration in Mexico. Consequently, the lack of a sanitary registration becomes the governing criterion for qualifying a product as a new molecule.

2. The role of the **New Molecules Committee** is limited by eliminating the prior technical meeting with the applicant, with the Committee's opinion being incorporated into the sanitary registration evaluation process. Additionally, where prior authorization from a recognized foreign authority exists, such opinion will only be required if associated risks are identified, thereby streamlining the procedure in certain cases.

3. The **patent linkage mechanism** is strengthened by aligning it with the applicable legislation and with the listings issued by the Mexican Institute of Industrial Property (IMPI). Additional requirements are introduced to evidence ownership or license rights and, in the case of generics and biosimilars, applicants may declare noninfringement of patents, with the authority being empowered to request a technical opinion from IMPI.

4. **Compensation for unreasonable delays** attributable to the authority is introduced in connection with the granting of sanitary registrations for allopathic medicines, where such delays affect the effective exclusivity period of a patent previously identified in the application. In such cases, the patent holder may request an adjustment to the term of one of the patents covering the medicine through a supplementary certificate, which may not exceed five years.

5. With respect to the **protection of test data**, a fiveyear exclusivity period is established for the technical and scientific information relating to safety, quality, and efficacy submitted to obtain the sanitary registration of medicines containing new molecules. During such period, this information may not be relied upon or used by third parties without the consent of the holder, which directly impacts access to the generics market.

6. The **term of sanitary registration renewals** is extended to align with the General Health Law, establishing that the first renewal is extended from five to ten years and that subsequent renewals are generally granted for additional tenyear periods.

The amendment seeks to reduce regulatory uncertainty, strengthen the protection of innovation, and align Mexico with international standards. The changes relating to patent linkage and regulatory compliance are particularly noteworthy. However, it will be necessary to assess their scope on a casebycase basis and, where appropriate, to make strategic adjustments to regulatory and industrial property planning.

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