Contacto CONAMER JBDLR-B00025061 2

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Para: Contacto CONAMER
Asunto: COMENTARIOS - Acuerdo colaboración IMPI y COFEPRIS
Datos adjuntos: Comentarios FIFARMA.pdf

Buenos días,

Por medio de la presente, enviamos los comentarios de la Federación Latinoamericana de la Industria Farmacéutica (FIFARMA) respecto al Acuerdo que establece disposiciones sobre la colaboración entre el Instituto Mexicano de la Propiedad Industrial (IMPI) y la Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS).

Quedo atenta a cualquier duda o comentario.

Saludos cordiales,

Raquel Sorza
Directora de Comunicaciones y Operaciones
FIFARMA

FIFARMA Comments on the Draft Collaboration Agreement Between IMPI and COFEPRIS

The Latin American Federation of the Pharmaceutical Industry (FIFARMA) recognizes and values the ongoing efforts of the Mexican Institute of Industrial Property (IMPI) and the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) to strengthen patent protection and prevent infringements related to biosimilars and generics. We see an opportunity to enhance key aspects of the regulatory framework to reinforce the system and align it with Mexico's international commitments.

Mexico, pursuant to its international obligations, needs to establish a comprehensive patent enforcement system that includes all product patents, such as use patents, and ensures reasonable notification and an opportunity for stakeholder participation. The current Draft Resolution falls short of satisfying these obligations.

Enhancing Patent Enforcement for a Stronger Innovation Ecosystem

Since the Federal Law for the Protection of Industrial Property came into effect in November 2020, the absence of implementing regulations has created uncertainty around patent enforcement. By establishing clear and predictable mechanisms, Mexico can:

- Ensure the early resolution of patent disputes before infringing products enter the market.
- Provide greater predictability for all stakeholders, including generic and biosimilar manufacturers.
- Safeguard market stability and ensure continuous patient access to medicines.

To achieve these goals, Mexico should facilitate:

1. Timely notification to patent holders when third parties apply for marketing approval.
2. Sufficient time and opportunity for patent holders to seek provisional remedies (e.g., injunctions).

We appreciate the opportunity to contribute to strengthening Mexico's patent system and aligning it with international best practices. To reinforce legal certainty and ensure compliance with Mexico's international commitments, we recommend that the agreement explicitly establish the eligibility of use patents for inclusion in the Gazette of Patents in Force for Use in Allopathic Medicines, ensuring their coverage under the IMPI-COFEPRIS patent linkage system.

Additionally, while Article 9 formalizes COFEPRIS' existing practice of publishing applications for marketing authorization of biosimilars and generics, it does not specify the frequency or content requirements for such publications. Therefore, we consider it essential to strengthen notification and engagement mechanisms to enhance transparency, legal certainty, and alignment with international commitments.

We appreciate your leadership in this process and reaffirm our commitment to working together to advance solutions that benefit all stakeholders.