Contacto CONAMER GLS-CVLS-AMMDC-B000222626

De: Suzette Kox <skox@igbamedicines.org>
Enviado el: lunes, 25 de julio de 2022 10:56 a. m.
Para: Contacto CONAMER
Asunto: NOM-177-SSA1-2013-IGBA comments
Datos adjuntos: NOM-177-SSA1-2013_IGBA comments.pdf

Dear Mr. Alejandro Ernesto Svarch Pérez,

Please find attached the IGBA comments regarding the COFEPRIS' draft modifications of the existing biocomparable products guideline NOM-177-SSA1-2013, in addition to our comments submitted already via your dedicated website. We trust that our contribution is being considered during the finalization of this guideline.

Please do not hesitate to get in touch for further clarification. Thank you.

Best regards,
Suzette

INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

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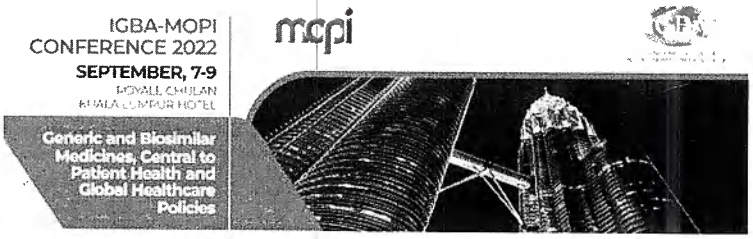

INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

Geneva, 25 July 2022

Attn.:
El Comisionado Federal para la Protección contra Riesgos Sanitarios
y Presidente del Comité Consultivo Nacional de Normalización de Regulación y Fomento Sanitario
Mr. **Alejandro Ernesto Svarch Pérez**
COFEPRIS

Ref: COFEPRIS' draft modifications of the existing biocomparable products guideline NOM-177-SSA1-2013

Dear Mr. Alejandro Ernesto Svarch Pérez,

Please let me first introduce IGBA, the International Generic and Biosimilar Medicines Association. We are a global industry association, which strengthens cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. Adopting a patient centric approach, IGBA works to improve patients' access to quality-assured, safe and cost-effective medicines by promoting competition and enabling innovation in the pharmaceutical sector.

In many countries around the globe, the use of biosimilar medicines has triggered competition in the originator biologic medicines market, allowing for treatment cost-efficiency gains in the therapy areas in which they are used. However, the pre-requisite is a well-functioning biosimilars market to ensure broader, timely, stable, affordable and sustainable access to biologic therapies patient access. This encompasses increased efficiency of biosimilars regulatory frameworks, which are a key enabler of greater access to quality-assured biologic medicines.

IGBA, therefore, welcomes the opportunity to comment on COFEPRIS' draft modifications of the existing biocomparable products guideline NOM-177-SSA1-2013. It is acknowledged that biocomparable products developed and manufactured outside of Mexico can seek marketing authorization / licensure in Mexico based on biocomparability data that have been generated **outside** of Mexico, including all **clinical** biocomparability data. The present draft modifications introduce a novel requirement for the renewal of a biocomparable product marketing authorization, which – at the time of marketing authorization / licensure **renewal** - asks for additional clinical biocomparability / interchangeability data generated in Mexican subjects by authorized third parties in Mexico.

About IGBA

The International Generic and Biosimilar medicines Association (IGBA) strengthens cooperation between associations representing manufacturers of generic and biosimilar medicines from around the world. Adopting a patient centric approach, IGBA works to improve patients' access to quality-assured, safe and cost-effective medicines by promoting competition and enabling innovation in the pharmaceutical sector and sustainable economic contributions for all stakeholders. For more details, regarding IGBA and its member associations, see the IGBA website at: www.igbamedicines.org.

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We ask COFEPRIS to **waive** this novel requirement for renewal applications; to our understanding, a renewal application should not go beyond updating the initial dossier, e.g., manufacturing, product testing, or product safety updates. This is also in line with international regulations and avoids divergent international requirements. Convergence of requirements is paramount to support worldwide access to life-saving biological medicines. IGBA is happy to provide further scientific input as why local clinical data generation is not at all appropriate for biosimilar medicines.

We thank you for your consideration.

Yours faithfully,

Suzette Kox
IGBA Secretary General