THE CRITERIA FOR THE RECOGNITION OF AUTHORIZATION OF RESEARCH PROTOCOLS ISSUED BY A FOREIGN REGULATORY AUTHORITY HAVE BEEN PUBLISHED

MAY 19, 2025

Executive Summary:

- In accordance with the General Health Law, the Ministry of Health is responsible for coordinating research involving human subjects, which may be authorized for preventive, rehabilitative, or research purposes, even in cases where there is insufficient scientific evidence of its therapeutic efficacy, or when the therapeutic indications of already known products are to be modified.

- Additionally, the Law establishes that the Federal Commission for the Protection against Sanitary Risks ("**COFEPRIS**") is responsible for the evaluation, issuance, and revocation of health-related authorizations, as well as for the exercise of regulatory, control, and health promotion authority.

- Based upon those premises, as from January 4, 2013, the Official Mexican Standard NOM-012-SSA3-2012 was published in the Official Gazette of the Federation ("**DOF**"). This standard establishes the administrative, ethical, and methodological regulatory criteria for the authorization, execution, and monitoring of projects and protocols for research purposes involving the use of drugs or materials in human subjects.

- However, in an effort to maintain the regulatory framework current with the times in the pharmaceutical industry, the Ministry, on March 24, 2025, published in the DOF, the *Agreement establishing the criteria for the authorization of research protocols involving human subjects that have been previously authorized by a Foreign Regulatory Authority* (the "**Agreement**"), thereby providing for the *"Reliance" procedure*.

The purpose of the Agreement is to establish the list of Foreign Regulatory Authorities ("**FRA**") and the criteria for recognizing the authorization of research protocols issued by an FRA through a procedure based on trusted regulatory practices, known as the *"Reliance"* procedure, as well as the criteria for granting such authorization exclusively for research involving human subjects.

"*Reliance*" refers to the act through which a public institution or body, authorized to exercise independent regulatory oversight over the development, production, market authorization, and surveillance of medical products within its jurisdiction — referred to as the National Regulatory Authority ("**NRA**") — takes into account and attributes significant weight to assessments conducted by another regulatory authority or trusted institution (FRA). This results in a process of streamlining and updating efforts, allowing for resource optimization and the reduction of costs and administrative processing times[1] in the approval of research protocols of new molecules or the use of different indications of an existing pharmaceutical.

The acceptance of international standards must be based on evidence that the authorizations issued by the FRA have undergone a comprehensive and independent review by said authority, and that the FRA's requirements are sufficient to meet the regulatory requirements of the NRA, which shall remain responsible for the decisions made and accountable for them.

Moreover, applications must be submitted through the COFEPRIS procedures and services platform ("**DIGIPRiS**"). The requirements for submission include a certified, legalized, or apostilled copy, along with a Spanish translation, of the clinical protocol authorization issued by the FRA, which must have been issued no more than one year prior. Additionally, an English copy of the Investigator's Handbook and Protocol, which was used to obtain the authorization, must be provided, as well as a Spanish version that has been approved by the relevant committees in Mexico.

Finally, the Agreement states that COFEPRIS will consider decisions based on "Reliance" regulatory practices from the European Medicines Agency ("**EMA**"), the United States' Food and Drug Administration ("**FDA**"), the United Kingdom's Medicines and Healthcare Products Regulatory Agency ("**MHRA**"), and the Canadian Health Agency ("**Health Canada**"). COFEPRIS shall have the authority to deny authorization of the research protocol if there is sufficient evidence of a lack of safety, quality, efficacy, purity, or stability of the protocol, or if there are serious risks to research subjects.

TRANSITIONAL ARTICLES

- The Agreement will enter into force 60 business days after the date of its publication in the DOF, which is on June 19, 2025.

We are at your service for any information related to the impact or scope of this Agreement on the recognition of authorization of research protocols.

[1] Comisión Federal para la Protección contra Riesgos Sanitarios. (2021). *Estudio de caso. Reliance, COFEPRIS y el ámbito internacional.*

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