Expert Contributor

The Protection of Clinical Data in Mexico Still a Pending Issue.

By Alejandro Luna F.
Thu 27/02/25

In Mexico, a couple of decades ago, the protection of clinical data was a little-known legal figure, in addition to having been disregarded for many years, although Mexico had already acquired certain international obligations to attend to and recognize this right, which mainly prevents unfair competition and illicit enrichment.

There is still an absence of domestic regulation in Mexico regarding such important protection and a form of attraction and access to new, safe and effective products, as well as the incentive for the development of new and more clinical studies, both for novel products, as well as new formulations, presentations, and indications. After more than 25 years of Mexico's flagrant disregard of the obligations of international treaties to recognize the figure, both in TRIPS and NAFTA, it is time for Mexico to adopt this figure in its domestic legislation and thus avoid the uncertainty and judicialization of the figure.

Despite the differences in the object of protection (active ingredient, formulation, pharmaceutical form, indication, orphans) and its duration, as well as the transition periods established in the different international treaties – TRIPS, TIPAT, and T-MEC – the implementation and domestic regulation of the figure cannot be delayed any longer, otherwise, uncertainty and judicialization will not only affect innovators but all actors involved in the health system, including patients.
Therefore, comparative law can also be considered to include clinical data protection in domestic legislation. For the implementation to comply with international commitments, and to avoid judicialization and interpretation, it is suggested that domestic legislation includes the following normative propositions:

- Subject matter of protection for clinical data for new chemical entities, new indications, new formulations or forms of administration, as well as biological and biotechnological products.

- To establish that, for obtaining protection, data is required to obtain safety or efficacy.

- Data should not be disclosed, except for those required to protect human health; for example, those extracts required by domestic or international legislation to comply with health advertising requirements.

- It is not necessary to make considerable efforts to obtain the data, since it is implicit in the applicable legislation and regulation.

- Expressively state that the protection includes the non-reliance of innovator’s information.

- To define the scope of direct and indirect use of protected data.

- Establish the duration of data protection of at least three years for new formulations and new indications.

- Establish the duration of at least six years of data protection for new chemical entities, as established by Mexico's commitment to the European Union and/or homologate the minimum term established in the USMCA.

- For biological and biotechnological products, a minimum term of 10 years of data protection can be established, during which no person may rely directly or indirectly on the originator's data, and two years of commercial exclusivity, during which any third party may rely on the originator's data from the 10th year but may not obtain sanitary authorization until the 12th year. Other jurisdictions and business partners use these mechanisms of protection.

This proposal suggests a commercial exclusivity period, during which any third party may rely on the originator's data two years before the expiration of protection, in order to avoid an additional exclusivity period.

- Specify the start of protection in Mexico as well as the requirements for its recognition, providing for studies carried out abroad, ownership, co-ownership, and authorizations to third parties.

- Establish a procedure for requesting protection, the corresponding certificate, how the protection will be applied and enforced.

I understand the difficult task of the legislative or regulatory efforts to establish the Regulatory Data Protection in our country, which will be well-suited within the public health policies; however, the lack of such regulatory efforts will cause greater negative impacts on the ecosystem of the pharmaceutical industry in our country.

Alejandro Luna F.
OLIVARES Partner