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Regulatory authorities in many countries, including Mexico, require the applicant for a marketing authorisation for a new drug to provide data concerning the safety and efficacy of that drug. A company that develops a drug does not have an option, when bringing it to market, other than investing in the generation of all the corresponding data, including clinical trials, with the expenses usually being covered by the developer.

The process of proving that a drug is safe and efficient implies a significant investment of time and money. At the pre-clinical stage, testing is performed on animals in order to determine whether a medication has positive effects on sick animals and whether it lacks secondary effects in healthy animals. Most drugs do not get past this pre-clinical stage.

Based on the pre-clinical results, strict protocols are drafted to perform safety and efficacy testing in humans, which requires authorisation by the regulatory authorities. The studies imply large investments (which in 2007 averaged at $800 million per product) and can take between 10 and 15 months to complete. As a result of this process, the equivalent of thousands of pages of data on clinical studies is generated, and charts and graphs are necessary to interpret the data. The information package as a whole constitutes a dossier, which is submitted before the health authorities. Even when, occasionally and for promotional purposes, the results of these clinical trials are published, the information package and the bulk of the data generally remain confidential.

In this sense, a very important part of the costs related to obtaining a marketing authorisation for an innovative drug derive from the necessity to undertake clinical studies of safety and efficacy.

The need to make this investment in order to get a drug approved carries a double-sided problem from an economic perspective. On one hand, if the party

generating such data cannot recoup the investment made, it would simply not be effective, from a cost-benefit standpoint, to develop or launch a new medication on the market, thus affecting patients who could have been helped by it. On the other hand, forcing each and every applicant for a marketing authorisation for a generic product to repeat every one of the studies made by the innovator would serve no specific technical purpose and would delay entry into the market of competing products, with a corresponding impact on final prices.

In light of this, a balance is needed to ensure the right incentives to bring new drug products onto the market and to encourage fair competition.

TRIPs and NAFTA

On this specific issue, Mexico is part of the TRIPs and NAFTA international agreements, both of which set forth obligations for the signing parties to protect undisclosed data on the safety and efficacy of pharmaceutical products, required by the regulatory authorities in order to obtain marketing authorisations.

Whereas the wording of TRIPs, specifically the obligation to protect data against unfair commercial use, has been subject to different interpretations concerning which actions would constitute unfair use, NAFTA contains different language, specifying the nature of this protection.

Sections 5 and 6 of NAFTA Article 1711 are relevant to this issue. Section 5 sets forth that undisclosed test or other data on the safety and efficacy of a product, which involves considerable effort, will be protected against disclosure, except where such disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

Section 6 addresses a different concern, setting forth that undisclosed data on safety and efficacy will be protected against reliance from third parties for a period of time no less than five years. Furthermore, upon respecting this non-reliance period, there will be no limitation on any party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.

The US and Canada have already established legal frameworks to comply with this obligation, understanding that the term reliance refers to both: (i) accessing the information upon studying a third party application (which has been defined as direct reliance); and (ii) drawing conclusions on the safety and efficacy of a second product, which has proven interchangeability without the need to access

the innovator's dossier (defined as indirect reliance), but Mexico seems to be going in the opposite direction.
Until December 2007, the legal framework in Mexico pertaining to this issue was the following.

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· Article 86 of the Mexican IP Law establishes that information required by law to determine the safety and efficacy of pharmochemical or agrochemical products using new chemical compounds will be protected according to the international treaties subscribed to by Mexico. This Article is in the Industrial Secrets chapter of the IP Law.

· Article 167 of our Health Law Regulations states that all confidential information filed in order to obtain a marketing authorisation must be protected against disclosure (without any mention on reliance).

· The Information Access Law establishes that information will be considered confidential when a body of law expressly considers that certain information should be protected. Also, this law mentions that industrial secrets will be considered confidential information.

· There was no specific provision protecting information against reliance and the requirements on safety and efficacy of a product were not differentiated in the Health Law regulations for innovative or generic products. Whereas this differentiation was applied in practice by COFEPRIS (the administrative office in charge of granting marketing authorisations), the applicable provision was the same for all applicants requiring technical and scientific information on safety and efficacy.

Recent provisions

On January 2 2008, a decree was published in the Official Gazette modifying several provisions of the Regulations for Health Consumables of the Health Law to address several aspects relevant to the pharmaceutical market.
These regulations eliminated the distinction between generics and interchangeable generics. Before the regulations were enacted, a marketing authorisation could be obtained for a generic product without the need for bioequivalence or bioavailability studies, in which case the products would be considered as generics, similars or trade mark generics, and those that had proven interchangeability would be included in the interchangeable generics catalogue.

Following the reforms, all generic medicines will need to prove interchangeability with an innovative medication before 2010.

The relevant part affecting DPE rights is that, within the amendments concerning generic medications, the specific requirement to prove safety and efficacy was eliminated and substituted by the need to prove interchangeability. The Health Law regulations were modified to implement an abbreviated approval procedure for generic drugs, on the basis of bioequivalence and bioavailability studies, without setting forth any provisions concerning a non-reliance period.

Challenges

Therefore, in addition to possible breaches of DPE rights before January 2008, the Mexican R&D industry is seeing the automatic entry of generic products onto the market, as the COFEPRIS can neither observe the five-year period nor require information from the generic product applicant, other than studies of interchangeability.

Our firm has participated in challenging the constitutionality of the January reforms to the Health Law Regulations, as well as in additional court actions seeking a judicial interpretation of the contradictions that have been summarised here. These actions are still in process, but a stay has been ordered by an administrative court in one of the proceedings forbidding the COFEPRIS from granting an authorisation relying on the innovator's data until the trial is decided.

The only current initiative of the Mexican Health Authorities is to address the issue through regulations that will apply to the New Molecules Committee, a body that will have jurisdiction in the approval process for new products. The project for these regulations, which was provided to R&D industry participants in Mexico, establishes that only confidentiality concerning data will be observed, and that such confidentiality will be limited to a five-year period, which would constitute an additional breach of the NAFTA obligations. If this project is passed, it is also likely to be subject to a constitutionality challenge.

The current Mexican regulatory framework leans towards the encouragement of generic competition, providing quick access to markets without taking due care to comply with NAFTA obligations, which have as an underlying purpose the establishment of proper incentives to bring new drugs to market.

The second possibility for changing this situation is a proposal to reform the Health Law Regulations in order to correctly implement NAFTA obligations,

based on the Canadian example, which has been submitted to our health authorities for consideration and is now under examination.