Mexico

Recent developments in clinical data exclusivity

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The historic evolution of data exclusivity in Mexico

Mexico, along with the United States and Canada, was one of the first countries to sign data protection provisions in a free trade agreement. The North American Free Trade Agreement (NAFTA) included obligations related to the protection of data submitted before regulatory agencies well before the Agreement on Trade-Related Aspects of IP Rights (TRIPs).

Paragraphs 5 to 7 of Article 1711 of NAFTA contain specific provisions with regard to data submitted to entities in charge of granting market approvals for pharmaceutical and agrochemical products, with the main obligation imposed on the contracting states to prevent unfair commercial use of such information.

NAFTA has always been considered a more specific standard for the protection of clinical data than TRIPs, as it provides for a minimum standard of five years of protection from the date that market authorisation was granted.

However, such paragraphs are not as clear as intended, allowing compliance with the treaty by simply keeping the information confidential.

Mexico has enacted no specific national provisions that could facilitate the interpretation or implementation of the treaty.

The only reference to the treaty is included in the Industrial Property Law, which states in Article 86*bis* that any information required for determining the safety and efficacy of pharmaceutical and agrochemical products using novel chemical compounds shall be protected under the terms of the international treaties to which Mexico is party.

For many years, the results of clinical trials submitted to the health authorities were not published or otherwise made available to the public. The government argued that this was in compliance with the treaties because the information collected was kept confidential. In fact, not a single case of grant of a generic drug approval (before the five-year period mentioned in TRIPs and NAFTA) had been documented, perhaps because of the existence of patents covering longer periods.

Accordingly, data exclusivity enforcement in Mexico was theoretically difficult because not all drugs commercialised after a first approval required bioequivalence tests — so-called 'lookalikes'. Accordingly, Mexico was technically not obliged to prevent unfair commercial use because the information of the drug which had been approved first was not publicly available from the Federal Commission for the Protection against Sanitary Risk and therefore not 'used' by generic manufacturers.

Since February 2008, modifications to the Health Supplies Regulations have led to the elimination of lookalikes and interchangeable generics, for which registration was based on general public data, by providing for only two kinds of drug:

- innovator drugs, based on information from clinical trials; and
- generic drugs, based on bioequivalence tests without the need for full clinical trials.

Although growing concerns regarding the quality of lookalikes drove these changes, inadvertently they also made applicable one of the specific rules under NAFTA for the five-year protection term.

NAFTA provides for the data exclusivity of bioequivalence testing because the grant of

generic drugs based on such testing is expressly included as possible if the five-year protection term is granted. However, the enactment of specific laws supporting such interpretation was still missing, as no court or administrative precedents could support such an interpretation.

In practice, there were still no cases of grants of generic drug approvals within five years from the date of first registration of a drug in Mexico, although there have been attempts that are still under litigation.

However, under new definitions incorporated into Mexican law, 'innovator medicaments' were defined as medicaments using or constituting new molecules, combinations of drugs that were not used formerly in Mexico, new indications or new formulations – all of which required the generation of clinical data and therefore, in principle, were protected by NAFTA.

Further legal developments included the enactment of provisions related to biotechnology drugs and bio-comparable (biosimilar) drugs. However, no provisions were raised regarding the possibility of a higher term of protection for such drugs.

Congress made some effort to compile an amendment regulating NAFTA and TRIPs obligations in the General Law on Health, by considering a longer term of between eight to 12 years for biotechnology drugs. Under the provisions related to such drugs, biotechnology drugs were considered simply as traditional chemical drugs with no differentiated treatment.

With the imminent change in government, the negotiations on such an amendment to the law were halted.

However, as the G20 forum was held in Mexico in June 2012 and Mexico wanted to enter negotiations for the Trans-Pacific Strategic Economic Partnership Agreement, the government was urged to deal with three important pending IP issues:

- the Madrid Protocol;
- the Anti-counterfeiting Trade Agreement; and
- data exclusivity for pharmaceutical products.

In terms of data exclusivity for pharmaceutical products in particular, as the obligation of international treaties is imposed on contracting states, the government decided to enact such provisions through a set of internal rules that are mandatory only for Federal Commission for the Protection against Sanitary Risk officers.

The new rules

The Guidelines for the Protection of Confidential Information of Medicines containing Pharmachemicals as a New Chemical Entity were published on June 18 2012. The Federal Commission for the Protection against Sanitary Risk expressly stated that the confidential information received in conjunction with a health approval application is subject to protection against unfair commercial use and public disclosure according to NAFTA and TRIPs. Such information is subject to a five-year term of data protection in Mexico, from the date that approval is granted.

As already mentioned, as a matter of law, these guidelines are mandatory only for Federal Commission for the Protection against Sanitary Risk officers, but are not necessarily applicable in general to applicants applying for either new drugs or generic drug approvals, since they have only internal effects.

The guidelines expressly refer to Article 167 of the Health Supplies Regulations, which relates to data subject to protection according to international treaties. This article, in turn, describes the requirement to submit scientifically evidenced safety and efficacy data, which is therefore now recognised as subject to protection under the treaties for the first time in Mexico since NAFTA was signed.

On the other hand, the guidelines place a burden on the data owner of determinations that correspond to the Federal Commission for the Protection against Sanitary Risk. For example, the guidelines state that protection will be granted if the applicant proves that the submitted data relates to pharmachemical products that:

- use "new chemical components";
- are related to safety and efficacy under the Health Supplies Regulations;
- remain unpublished or were published in order to protect the public;
- were protected against unfair commercial

use by certain measures; and
- for which the data was obtained through considerable effort.

It seems that the rules intended for internal officers of the Federal Commission for the Protection against Sanitary Risk place a burden on the applicant of a sanitary registration of a new drug, since on the one hand officers must evaluate the submitted data, but on the other hand submission of such data by the applicant of a new drug approval is not mandatory.

For bio-comparable drugs, the guidelines refer only to Article 167 of the Health Supplies Regulations, without mentioning Article 177, which refers to data requested for the approval of biotechnology medicaments.

The drafting of the rules in the form of guidelines seems to have the intention of specifically excluding data related to formulations or new indications and also all data related to bio-comparable drugs. The omission of Article 177 and the emphasis on the terms 'new chemical component' and 'new chemical entity' in the guidelines seem to support such an approach by the Federal Commission for the Protection against Sanitary Risk.

However, due to the different definitions used in the guidelines and the lack of consistency due to the use of terms that were not defined under applicable Mexican law, other interpretations seem possible, and the final effect is still to be determined.

One such inconsistency relates to Articles 166(III) and 2 of the Health Supplies Regulations. Under this law, medicaments for which safety and efficacy must be demonstrated based on information from clinical trials are those containing 'new molecules'. The term, as mentioned above, comprises new molecular entities, but also drugs or combinations of drugs that were not used previously in Mexico, new indications or new formulations. Therefore, it might be possible to interpret that the terms 'new chemical component' and 'new chemical entity' are synonymous with the term 'new molecule', as this is the only term defined as such in Mexican law. However, this is not a straightforward issue.

The guidelines further fail to clarify the scope and nature of the protection resulting from a mix of language and concepts that are inconsistent with Mexican law, for example, use of the terms 'pharmachemical products', 'pharmachemical medicines' and 'new chemical components', instead of the clearly defined term contained in Article 221 of the Law on Health: 'medicament'.

The terms 'pharmachemical products' and 'pharmachemical medicines' are unclear, since they are undefined within the law; therefore, it is open to debate whether the regulations are illegal since they contemplate terms that are not established in Mexican law, TRIPs or NAFTA. Likewise, the term 'new chemical component' is used indistinctly with the term 'new chemical entity', instead of 'new molecule' — a term also expressly defined in the Law on Health. This situation has led to discussions regarding the real intention of the guidelines when these different terms were cited.

What to expect

As explained above, the rules do not seem to clarify and implement in full the scope of NAFTA or TRIPs provisions. Instead, the new guidelines generate uncertainties that formerly did not exist, such as the term for biotechnology drugs (if any) and the applicability of the protection to data other than for new chemical components.

Therefore, there is still the need for a specific amendment that can consider all of the aspects of an efficient implementation of both treaties (ie, NAFTA and TRIPs), perhaps through amendments which align the guidelines with Mexican law by enacting a specific law regarding compliance with the treaties. Such an amendment must be executed directly into the law, or at least into the regulations, but not simply through internal regulations which are applicable to only the Federal Commission for the Protection against Sanitary Risk (as occurred with these new rules), otherwise the nature and legality of the disposition that contemplates the date exclusivity provisions will always be a point of debate.

As the guidelines are implemented and used by Federal Commission for the Protection against Sanitary Risk officers in their decisions, litigation cases from generic manufacturers and/or affected data owners may arise which

challenge the regulations *per se* or also challenge decisions issued by the commission grounded on this guidelines, under the main argument that internal dispositions cannot be applied to the general public.

In addition, it is also probable that the application of these guidelines will derive in litigations that will claim lack of clarity in the scope of the guidelines and lack of clarity in the language and wording of the provisions. Litigation might arise from both innovators and generics, depending on the way that the commission interprets the provisions.

This seems to be the most likely scenario, considering that with the change of government in Mexico, the passing of the law that is still pending in Congress seems unlikely.

However, as Trans-Pacific Strategic Economic Partnership Agreement negotiations progress, and the obligations related to IP enforcement and compliance advance, we may also see some willingness from the government towards more specific implementation, with the main aim being a clear position regarding biotechnology drugs. **iam**

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