New Mexican marketing authorisation and data exclusivity regulations

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On 2nd January 2008 a decree was published in Mexico's *Official Gazette* modifying several provisions of the Health Law Regulations for Health Consumables. The changes have important implications for the pharmaceutical industry.

First of all, the amendments have eliminated the distinction between "generics" and "interchangeable generics". Previously, the regulations recognised "interchangeable generics" only. References to the former list of "interchangeable generics" and to this type of registration have been removed.

In addition, under the amended regulations, a generic registration can now be obtained only through evidence of interchangeability or bioequivalence.

> *"ARTICLE 2*
> *... XIV. Generic Drug, the pharmaceutical specialty with the same drug or active ingredient and pharmaceutical form, with the same concentration or potency, which uses the same administration route and by means of the required regulatory tests, has proved that the pharmacopoeia specifications thereof, dissolution profiles or bioavailability or other parameters, as the case may be, are equivalent to the referenced drug.*
> *XIV* Bis*. Referenced Drug, the drug indicated by the Ministry of Health as such, that counts with the registration of said agency, which is available commercially and that is selected pursuant to the criteria established in the official regulations."*

Also in regard to generic medicines, the prior specific requirement to prove safety and efficacy has been replaced by a sole requirement to prove interchangeability. This may impact on data exclusivity issues, as reliance on the information of the reference product appears to be necessary for the issuance of generic authorisations. In the author's view, the amendments will therefore undermine data exclusivity in Mexico, as they expressly eliminate the need to provide safety and efficacy tests for generic applications, requiring only that interchangeability tests be provided. To explain these implications in full, it is necessary to begin with a discussion of data exclusivity protection in Mexico.

Data exclusivity under NAFTA and TRIPs

Under the North American Free Trade Agreement (NAFTA), any undisclosed information submitted in order to obtain marketing authorisation shall be protected from copying by third parties for at least five years. This period, according to Article 1711 of NAFTA, shall begin from the date on which the marketing authorisation is granted to the requesting party.

NAFTA's wording is subject to interpretation as regards reliance on the product safety and efficacy data contained in the dossier, since Article 1711, Section 6 reads as follows:

> *"6. Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and*

the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies."

The provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) should also be taken into account – specifically Article 39.3 on the protection of data from unfair commercial use, which links this protection to Article 10*bis* of the Paris Convention. TRIPs does not specify a minimum term of protection.

These international provisions are complemented by provisions of national law, as follows:

- The IP Law establishes that undisclosed information in an application for marketing authorisation shall be regarded as a trade secret. It also states that information submitted in order to obtain authorisation to produce or market chemical products shall be protected according to the international treaties to which Mexico is a signatory.
- Article 167*bis* of the Health Law Regulations states that all confidential information filed in order to obtain a marketing authorisation must be protected against disclosure.
- The Information Access Law establishes that information will be considered confidential where a body of law expressly provides that certain information should be protected.

Under the amended Health Law Regulations, the manufacturers of generic medicines are entitled to obtain marketing authorisations for their products by providing dissolution profiles or bioavailability studies in relation to the innovator product, regardless of what would constitute an indirect reliance on safety and efficacy studies contained in the innovator's dossier.

Thus, while direct reliance or use of data contained in a dossier is forbidden under NAFTA, in Mexico an indirect reliance on such data is now generally allowed, since a generic applicant will benefit indirectly from the safety and efficacy studies contained in the innovator's dossier without any need to access these studies directly.

Therefore, under the existing legislation and the prevailing interpretation of international treaties to which Mexico is a signatory, there can only be a breach of data exclusivity in the event of disclosure or indirect reliance – both by the entity in charge of granting marketing authorisations in Mexico (known as COFEPRIS) and by a third party – if confidential information in a dossier were obtained, provided or accessed in order to obtain a marketing authorisation, which would constitute grounds for legal action based on NAFTA, TRIPs and local provisions.

Mexican jurisprudence indicates that international treaties are part of the Mexican legal system and take precedence over federal and local legislation. This would further reinforce the above conclusion concerning all dossiers filed from 1994 – when NAFTA came into force – to date.

Challenging a marketing authorisation issued in breach of data exclusivity

In Mexico, the main avenue for challenging an act of an authority is through a nullity trial before the Federal Court of Tax and Administrative Affairs. In this particular context, the action is brought against COFEPRIS for violation of the above-mentioned provisions. The object of this trial is the annulment of the marketing authorisation. It is possible to request that the effects of the marketing authorisation be stayed pending a decision; this stay is granted at the court's discretion.

The trial must be brought within 45 working days of learning that the marketing authorisation has been issued to a third party. The affected party can request the court to provide a copy of the dossier allegedly containing information obtained in breach of data exclusivity.

Pre-emptive actions may be bought against COFEPRIS for a failure to make the public aware of the existence of data exclusivity rights. Such an action is initiated by a written request to COFEPRIS for recognition of data exclusivity. A failure to respond or a negative response to this request may be contested before the court. A stay may also be requested which would prevent COFEPRIS from issuing marketing authorisations that make reference to the dossiers at issue until the case has been decided. This option has been successfully tested: a Mexican court recently issued a preliminary injunction ordering COFEPRIS to refrain from granting any marketing authorisation that violates or relies on the data of an innovative product.

Once a decision has been issued, any

affected party (including COFEPRIS or the holder of a marketing authorisation which is nullified) can bring a further appeal before a circuit court.

The chances of success in these cases will depend on whether, in the court's opinion, a clear breach of data exclusivity has occurred, but the action should be looked upon favourably by the Mexican courts.

In the event of a direct reliance on data, an affected party additionally has the option to bring a specific criminal or civil action against the officer responsible for the disclosure; this should be analysed on a case-by-case basis.

Implications of amended regulations

In the author's view, the new regulations will undermine data exclusivity, specifically as regards indirect reliance on an innovator's information, as COFEPRIS can interpret the regulations in a way that allows generic manufacturers and COFEPRIS itself to rely on the innovator's safety and efficacy data.

COFEPRIS can now claim that the granting of marketing authorisations to third parties that rely indirectly on an innovator's data does not violate data exclusivity, as under the amended regulations no independent tests to prove safety and efficacy are required, and to some extent the regulations force reliance on the innovator's dossier, as interchangeability tests alone are sufficient to obtain a generic authorisation.

Therefore, a constitutional action – a so-called "*amparo*" suit – should be filed claiming that the amendments to the Health Law Regulations are unconstitutional, as they contravene the international treaties to which Mexico is a signatory. There are two opportunities to file such a constitutional action:

- Within 30 working days of the date on which the regulations enter into force (ie, 18th March 2008).
- Within 15 days of learning that data exclusivity has been violated or disregarded by the granting of a generic marketing authorisation under the amended regulations.

If a favourable decision is ultimately obtained in this constitutional action, this would preclude the application of the new regulations in prejudice of the data owner to support the granting of marketing authorisations to third parties based on indirect reliance on the protected data.

Although data exclusivity is protected in Mexico as a trade secret, a criminal action alone is not enough to cancel unlawful marketing authorisations. The burden of proving violation of a trade secret is very high and the eventual cancellation of the marketing authorisation will not be achieved until the final resolution of the criminal proceedings. On the other hand, an action based on indirect reliance on protected data involves higher degrees of complexity in the action and in the arguments, based on constitutional issues and conflicts between domestic law and international treaties.

Finally, the recent amendments to the Health Law Regulations also extend the timeframes within which COFEPRIS must decide whether to issue a marketing authorisation, as follows:

- From 40 to 180 days for medicines that have previously been registered in Mexico.
- From 60 to 240 days for medicines registered abroad.
- From 90 to 180 days for new molecules.
- From 90 to 180 days for biological medicines.

These terms can be reduced by half if a

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favourable technical report is first obtained from an authorised third-party laboratory. However, the extension of these timeframes may justify arguments in legislative initiatives or judicial actions seeking patent term extensions which are also contemplated in Chapter 17 of NAFTA.

Finally, another relevant change addressed in the reforms is the establishment of rules on the renewal or extension of marketing authorisations. Accordingly, unless extended, marketing authorisations will remain in force for five years. The main requirements for an extension are a technical report on interchangeability in the event of changes affecting the pharmacokinetics of the medicament and a pharmacovigilance report.

An additional reform which was included in the original draft act and was widely discussed in the media concerned the elimination of the local facilities requirement ("*requisito de planta*"), but this does not appear in the final version.

The next few months will reveal the positive and negative implications of these reforms for the pharmaceutical industry in Mexico. At this point in time, the recommended action is to file an *amparo* suit challenging those regulations affecting data exclusivity, in order to prevent the eventual granting of generic authorisations in breach of these rights.