USMCA Entry Demands Amendments to Mexican Regulations

By Ingrid Ortiz | Mon, 08/10/2020

More than one year has passed since the agreement between the US, Mexico and Canada (USMCA) was completed at Buenos Aires, Argentina. The modernization of the well-known North American Free Trade Agreement (NAFTA), signed by the same three countries, the new USMCA finally entered into force on July 1, 2020.

This international treaty will, indeed, have an impact in multiple fields. Among the arenas that will be touched by this new agreement is intellectual property (IP). The US, Mexico and Canada envisioned a treaty with an efficient, high-standard IP chapter that is expected to provide solid protection and a good path to enforcement of IP rights. Within this chapter are provisions regarding the "Protection of Undisclosed Test or Other Data" in relation to pharmaceutical developments – the so-called data protection exclusivity (DPE).

The results of the exhaustive studies, trials and tests described in summaries, comparative graphics, statistics and other supporting elements, translate into the set of clinical data aimed at proving the quality, safety and efficacy of a medicine.

Around this information emerged the figure of protection of clinical data. This protection aims to create a commercial balance, allowing scientific research from the pharmaceutical industry to subsist, in order to promote better access to health for all the population.

Data regulatory exclusivity in Mexico is quite unique and different in many aspects as it is known in other jurisdictions. As a brief background, it is important to mention that currently, there is no specific body of legislation or regulation for DPE in Mexico, only international treaties. NAFTA, as a regional agreement, represented a close basis in relation to DPE in our country.

Within the domestic legal framework, there is only an internal official communication issued by the regulatory agency responsible for applying and enforcing the corresponding regulatory framework in relation to drugs, biologicals and medical devices: the Federal Commission for Protection against Sanitary Risks (COFEPRIS).

This authority issued this communication in 2012, providing guidelines that stated a five-year term of protection limited to new chemical entities. However, the guidelines provided in this internal official communication are very narrow. Also, this document did not mention how the protection would be observed and enforced. In addition, the legal value of these internal guidelines is very weak, especially to sustain the enforcement of DPE.

Based on the interpretation of international treaties, such as NAFTA and others to which Mexico is a signatory, regulatory data exclusivity for at least five years for new chemical entities, formulations, new indications, and orphan drugs has been obtained through litigation.

Concerning biologics, which are much more complex developments than a chemical molecule or other developments, a longer DPE length has been requested.

Such requests have been supported by international treaties, such as NAFTA, which provides that this protection should be at least five years, and the International Comparative Law, such as the US legislation, since that country is our trade partner in NAFTA, and in the new USMCA. Similarly, there are many jurisdictions that have understood and addressed the need to grant a greater period of protection for the clinical data related to biologics due to their nature and complexity and therefore, the great efforts that their development require.

Thus, the study of DPE concerning biologics has been done on a case-by-case basis. The courts have ordered the sanitary authority to duly analyze if a longer period of protection is applicable. Also, recent precedents have ordered COFEPRIS to recognize six and seven years of DPE for biological products.

The final text of the USMCA as signed in 2018 describes the periods of protection more clearly than NAFTA. However, at the end of last year, the governments of the US, Mexico and Canada signed a "Protocol of Amendment" to the agreement. This protocol, among other modifications, includes the elimination and modification of the provisions for new formulations or combinations and a new method of administration: at least three years for new indications and at least 10 years for biologics, keeping only at least 5 yeast for new chemical molecules.

Without those specific provisions, and with no domestic law, the uncertainty among the generics and innovative pharmaceutical industries continues. To win this protection, litigation would still arise against the eventual refusals of COFEPRIS to recognize regulatory protection for more than five years for biologics and at least three years for new indications.

In addition to those amendments, there is a period of transition to include the agreement's provisions in the Mexican legal system. If seen in retrospect, from the date that the old NAFTA entered into force, this could translate to a total of 31 years.

Those amendments, indeed, involve a bigger challenge since prior to the publication of the protocol of amendment, the agreement provided a much clearer picture concerning DPE. On the other hand, the amendments to the USMCA, do not necessarily mean they will result in adverse decisions since the wording of NAFTA, establishing "…at least five years of protection…" remains in the same. In other words, the scenario is practically identical to January 1994, when the old trade agreement came into effect.

Moreover, the period of transition should not have a negative effect on how things have worked so far. There are favorable precedents with that NAFTA wording, obtaining more than five years of DPE for biologics. Therefore, the main grounds for legal action to obtain regulatory exclusivity remain, as well as those grounds aimed at getting more than five years for biologics.

At this point in time, there is a new world to be discovered. There are great expectations within the pharmaceutical industry on how the entry into force of such a relevant international agreement will eventually impact DPE in Mexico.

Despite the lost ground due to the amendments, and the inclusion of a period of transition, it is important to remember that there are other international treaties that have been around for a while now, and would apply in DPE cases in Mexico while the corresponding regulation is enacted.

For instance, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is still in force, and implemented in the Mexican territory through the Code of Commerce. As well, the internal guidelines issued by COFEPRIS, along with several favorable legal precedents in this regard, remain.

Besides, other international treaties will eventually enter into force and may influence DPE matters. A good example is the Mexico-European Union agreement that binds the parties to recognize at least six years of DPE for both small molecules and biologics, although this treaty is also pending full implementation.

Therefore, it is undeniable that the current scenario for DPE in Mexico will be impacted by the entry into force of the USMCA, as there is space to explore the process of modifying the corresponding provisions and the final text of the agreement, among other facets.

However, the uncertainty is not as bad as it may appear at first sight. The fact that there are “new provisions” concerning DPE and a period of transition for the corresponding regulation to be issued should not be considered as an obstacle or an excuse to overlook DPE in Mexico.

It is also undisputable that there is enough legal precedents that should be observed in relation to DPE in Mexico. This means there is still a path to obtain and enforce such protection.

Furthermore, the modernization of the treaty should represent an opportunity for the Mexican government to work on the corresponding regulation that can provide clear guidelines regarding the “Protection of Undisclosed Tests or Other Data” that provides strong and effective protection and enforcement, and consequently would provide certainty to the pharmaceutical industry, whether generics or innovative.