Biotechnology Industry Organization

Mexico Is Obligated to Protect Test Data for Biological Pharmaceutical Products

What are Biologics?

Biologics are complex medicines that are manufactured using living organisms. These drugs are far more complex than most small molecule chemical drugs, and include many of the latest breakthrough medical therapies for serious and life-threatening illnesses such as cancer, multiple sclerosis, diabetes and HIV/AIDS, as well as many serious rare diseases. Due to their size and complexity, biologics generally cannot be scientifically characterized to the same degree as small molecule chemical drugs.

Biologics are Unquestionably "Pharmaceutical Products" Entitled to Test Data Protection

Pursuant to Article 1711(5)-(7) of NAFTA and Article 39.3 of the WTO TRIPS Agreement, Mexico is obligated to protect test data submitted to a regulatory authority to support approval of new biological pharmaceutical products. A new biological pharmaceutical product not previously approved in Mexico qualifies for this protection because (i) it is a "new pharmaceutical product" (i.e., it is used to treat human disease) and (ii) it utilizes a "new chemical entity" (i.e., it contains a previously unapproved active ingredient, such as a protein, which is a chemical compound).

Some have suggested that Mexico is not required under NAFTA or TRIPS to provide test data protection for biological pharmaceutical products, either because U.S. law did not consider biological products to be "pharmaceutical products utilizing new chemical entities" or because biological products were not given test data protection at the time of NAFTA or TRIPS. Both of these assumptions are incorrect. Several biological pharmaceutical products marketed before the conclusion of NAFTA and TRIPS, including human growth hormone and insulin, were regulated as "new drugs" in the United States and given defined periods of data exclusivity. Other biological products were regulated under a second legal authority in the U.S. that did not place any limit on the period of data protection – for those products, the data protection period was, in effect, infinite at the time of NAFTA and TRIPS.

Biological Pharmaceutical Products Are Entitled to Data Protection

The purpose of the test data protection obligations in NAFTA and TRIPS is to provide incentives for manufacturers of pharmaceutical products to perform the difficult, time consuming and expensive clinical investigations needed to prove a new pharmaceutical product is safe and effective. The justification for protecting test data generated for biological pharmaceutical products is just as strong as it is for any other type of new pharmaceutical product. In fact, biological products typically must satisfy more regulatory requirements than pharmaceutical products made by chemical synthetic methods. One

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reason for this is that biological products, unlike other types of pharmaceutical products, cannot be completely characterized. Consequently, the manufacturing processes used to produce biological pharmaceutical products are regulated, with any significant changes to these manufacturing processes requiring additional reviews by regulators. By contrast, the manufacturing processes used to make chemically synthesized pharmaceutical products are not typically regulated – instead, regulators rely on comparisons of each batch of a product to an earlier produced reference product.

Mexico's Major Trading Partners Protect Test Data Generated for Biologics

Mexico's trading partners consistently protect test data generated for biological pharmaceutical products.

- In 2010, the United States enacted legislation that permits a manufacturer of a "biosimilar" product to reference an earlier approved biological pharmaceutical product approved on the basis of complete clinical investigations. The biosimilar product, however, cannot be approved by the FDA earlier than 12 years after the referenced biological product was approved, or 12.5 years if pediatric investigations have been performed at the request of the FDA.

- Canada provides 8 years of data protection for biologics which runs from the date of authorization of the innovative biologic.

- Europe provides data and market exclusivity for innovative biological pharmaceutical products for 10-11 years. The European system provides 8 years of data exclusivity, coupled with two years of market exclusivity, which can be extended an additional year if significant additional clinical investigations are conducted by the innovator.

- Japan provides effectively 8 years of data protection through their system of post-marketing surveillance requirements, which prohibit biosimilar product entry until the surveillance period is complete.

- Korea has a system similar to that in Japan, which, in effect, provides 6 years of protection for test data for biological pharmaceutical products.

- Australia provides 5 years of test data protection for biological pharmaceutical products, and has adopted Europe's standards for reviewing biosimilar pharmaceutical products.

Thus, there is a consistent global practice of protecting test data generated for biological pharmaceutical products.

Conclusion

Mexico should recognize its existing treaty obligations requiring it to provide protection for test data generated for new biological pharmaceutical products, and follow global practices of granting such protection. Test data protection provides crucially important incentives for developers of biological pharmaceutical products, and encourages these developers to bring their products to market in Mexico. We strongly encourage Mexico to follow the global practice of protecting test data for these important pharmaceutical products.