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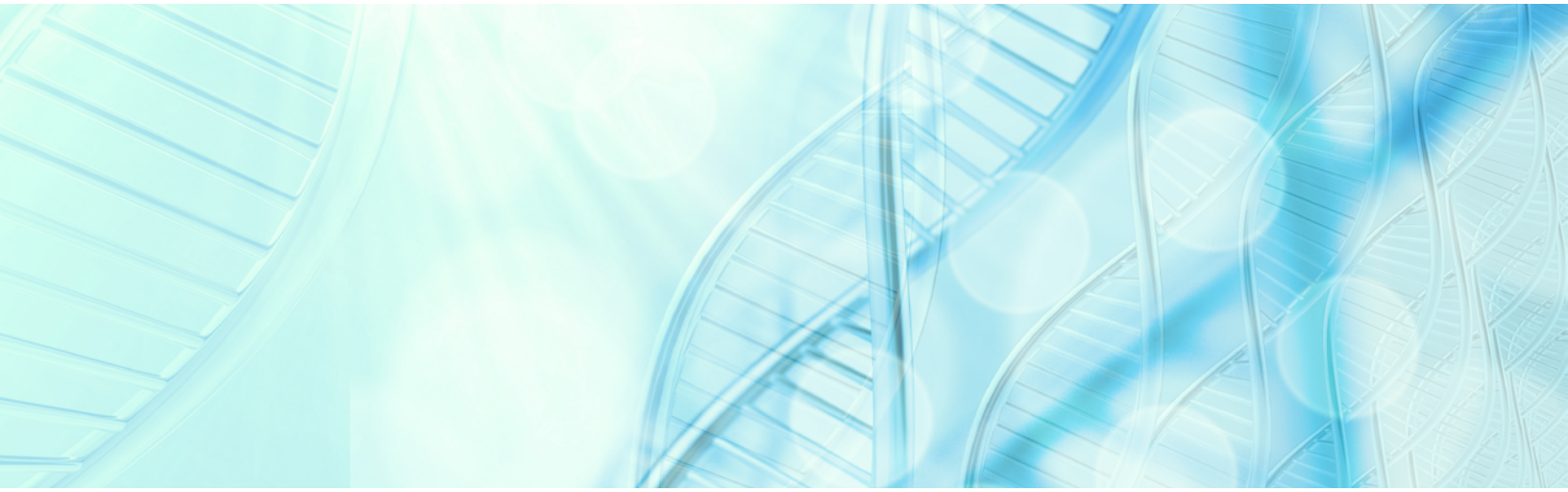
Life Sciences Industry Group Newsletter



Mexican Ministry of Health issues fast track approval process for products approved in other jurisdictions, and rules regarding import of drug products without need for a Mexican marketing authorization.

A communication was published on January 28 in the Federal Official Gazette establishing fast track approval processes, and formalizing the possibility to import drugs for sale without a Mexican marketing authorization. In this newsletter, we analyze the impact that these changes will have on the market, both for multinational and national pharmaceutical companies operating in our Country.

The Mexican Regulatory Agency (COFEPRIS by its initials in Spanish) had previously followed a policy of increasing approval/quality standards, in order to obtain reciprocal recognition. This has changed under the current administration, with a new focus on opening the possibility to bring in drug products from different markets in order to lower prices.

In line with this policy change, a communication was issued on January 28, establishing three main points:

I. Mexico now recognizes approval processes from several jurisdictions/WHO Bodies, and establishes a fast track proceeding for local approval.

The recognized jurisdictions/WHO Bodies are:

- Swissmed.
- EMA
- US FDA
- The Australian Administration of Therapeutic Products,
- WHO reference regulatory agencies.
- Products that have undergone WHO Prequalifications.

The fast track approval process consists of specific interchangeability requirements for generics and biosilimars (including Good Manufacturing Practices), and an additional need for favorable opinion from the New Molecules Committee to approve new products. According to this communication, all applications must be resolved by COFEPRIS within 60 days after filing.

II. The patent-marketing authorization linkage review is limited.

Under previous regulations/ practices, approval of a generic/biosimilar product, involved the Mexican Patent office; when an application was filed for one of these products, applicant was required to provide a statement/technical information in the sense that no Mexican patent associated to the drug product (compound, formulation or second medical uses) was being infringed.

This information would then be sent by COFEPRIS to the Mexican Patent office for verification, and the approval would not be issued until a favorable opinion was obtained.

According to the January 28 communication,

if the product seeking approval has a Mexican Patent in force covering the active ingredient/compound, a license must be recorded before the Mexican Patent Office before product approval. This limits linkage review in two main aspects:

i. Only active ingredient/compound patents will be taken into account (no reference to patents covering other aspects of a drug product, such as formulations)
ii. The requirement for analysis/clearance from the Mexican Patent office is eliminated.

III. Import of products is allowed without need for previous approval (or patent review)

In clear reaction to a broadly documented 2019 shortage of oncology related drug products, the January 28 communication establishes that the Ministry of Health, in coordination with other public institutions providing healthcare services in Mexico can import products without marketing authorization.

There are no standards to determine when these imports can take place; the only limitation is that an import of this nature can only take place once, as otherwise, a marketing authorization process is initiated.

Conclusions.

» Allowing fast track approval, under standards that may differ from those established in Mexico, will have an impact on business perspectives for the national pharmaceutical industry, as it may cause for an uneven playing field. Multinational companies (both on the generic and innovator arenas) may also object to this increase of competition with lower standards.
» Innovator companies can be affected by the limitation to linkage; under the new rules, it's not hard to envision scenarios where products are approved in violation of granted patents covering formulations or second medical uses.
» Import of products without need for approval can also have impacts, as this mechanism will likely be used to add pressure to companies in price-related discussion.

Our firm's Life Sciences team commonly acts as advisor to companies on relevant legal aspects Regulatory, Access, and IP crossover issues. Please contact us with any queries on the above.

This newsletter was prepared by Juan Luis Serrano-Leets (jlserrano@sanchezdevanny.com).

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