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Life Sciences Practice Group Newsletter

Administrative measures to expedite the marketing authorization process for foreign medicines and other health supplies

On November 18, 2020, the Ministry of Health published in the Federal Official Gazette the "Accord establishing administrative measures to expedite the marketing authorization process for foreign medicines and other health supplies" (the "Accord")".

Such Accord derived from the publication on November 11, 2020, of the "Accord wherein the Constitutional President of the United Mexican States instructs the Ministry of Health and the Federal Commission for the Protection against Health Risks (COFEPRIS), to conduct the granting of the marketing authorizations for health products in a period less than that established in the equivalence agreements executed by that date, and to establish shorter periods for future ones ("Accord 2")". Such accord intends to provide a larger number of Mexicans with access to more and better medicines and other health supplies.

The Accord establishes that COFEPRIS must make a determination on applications for marketing authorizations of foreign medicines and health supplies, within 5 working days of the applicant´s filing of the corresponding documentation.

If COFEPRIS does not give the applicant a response to such marketing application within the period established above, the application will be deemed to be authorized (deemed affirmation).

If the applicant is required to provide documents, clarifications or missing information, the abovementioned period will be suspended, and will resume on the working day following that on which the applicant provides said information, documents or makes the corresponding clarifications. If the applicant does not respond to this request, the application will be deemed as "not submitted".

For the purposes of the above-mentioned procedure, the health authority will have a period equal to one third of the period granted to solve the application (2 days) to require additional information or documentation from the applicant regarding a matter of administrative nature, and two thirds of that same period (4 days) regarding a matter of technical nature.

This Accord does not exempt importers, distributors or retailers of products that need to obtain said marketing authorization from complying with the requirements

established in Article 131 of the Health Supplies Regulations, or any other requirement or specification necessary to keep such marketing authorization, or from any other additional requirement to the marketing authorization procedure that must be met to market medicines or health supplies in Mexican territory.

The Accord entered into force on November 18, 2020.

Our team of experts can assist you in the preparation, filing and follow up of the marketing authorization application for the import, marketing and distribution of any foreign medicine or health supply that you may want to enter into national territory.

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