

The times are reduced for the sanitary registration in Mexico of certain medicines and health products

Yesterday the *“Ruling establishing administrative measures for facilitating the processing of the sanitary registration of medicines and other health products from abroad”* was published in the Official Federal Gazette, under which the Federal Commission for Protection from Sanitary Risks (COFEPRIS) must resolve the requests for sanitary registration of certain medicines and health products from abroad in a maximum period of 5 business days. Otherwise the registration request will be understood as approved.

Only medicines previously approved by any of the following foreign health authorities will be eligible: the Swiss Agency for Therapeutic Products-Swissmedic, the European Commission, the U.S. Food and Drug Administration, the Minister of Health of Canada, the Therapeutic Goods Administration of Australia, the Referenced Regulatory Agencies PAHO/WHO. The medicines prequalified by the Prequalification Program for Medicines and Vaccines of the World Health Organization or Regulatory Agencies that are members of the Pharmaceutical Inspection Cooperation Scheme are also eligible.

The only health products eligible are those that meet various requirements implemented and administered by the U.S. Food and Drug Administration, the Minister of Health of Canada and the Pharmaceutical Products and Medical Devices Agency of Japan.

The complete ruling can be consulted at this [link](#).

To obtain additional information, contact our experts:

Luis Miguel Jiménez, Partner:

+52 (55) 5258 1058 | lmjimenez@vwys.com.mx

María de Lourdes Salazar y Vera, Associate:

+52 (55) 5258 1058 | mlsalazar@vwys.com.mx

S I N C E R E L Y

VON WOBESER Y SIERRA, S.C.

Mexico City, November 19, 2020.