
MEXICO



This past 28 January 2020, the Mexican Federal Health Secretariat published a decision whereby the importation of medicines from other countries without a prior sanitary registration granted by the Federal Commission for Protection against Sanitary Risks (Comisión Federal para la protección Contra Riesgos Sanitarios-COFEPRIS) shall be permitted.

The fundamental arguments for the issuance of said decision are the following:

- To guarantee the correct provision of services by means of establishing a system to control the supply of medicines and their raw materials for health.
- To allow the purchase of medicines in any country around the world to prevent the shortage of supplies as occurs, for example, in the case of cancer medicines in other countries.
- To increase the stocks of medicines, which helps to reduce monopolies.

This decision allows foreign companies to import medicines that have not been granted a sanitary registration issued by the Mexican authorities.

It must be highlighted that a sanitary registration will continue to be necessary, but those registrations which are deemed as equivalent will be recognised as valid by means of a simple and quick administrative procedure, provided that they have been authorised by any of the following regulatory authorities: Swiss Agency for Therapeutic Products-Swissmedic; European Commission (European

Medicines Agency); USA Food and Drug Administration (FDA); Ministry of Health of Canada; Therapeutic Goods Administration of Australia; PAHO/WHO Reference Regulatory Agencies; previously qualified by the World Health Organization's Prequalification Programme for Medicines and Vaccines; or Regulatory Agency members of the Pharmaceutical Inspection Co-operation Scheme.

In the administrative procedure to obtain the sanitary registration, if there is a patent for the active substance or ingredient, the applicant shall be required to submit documentation showing that he is the owner of said patent or holds the corresponding license, and these documents must be registered in the Mexican Industrial Property Institute (Instituto Mexicano de la Propiedad Industrial, IMPI); the importance of the registration of licenses that may exist in relation to the patents also ensues.

**This decision entered into force the day after its publication,
that is, 29 January 2020.**