Expert Contributor

New Decree on Drug, Devices Importation Falls Short, Again

By Armando Arenas
OLIVARES Partner
Mon 01/20/25

As a response to the drug shortage in Mexico caused by an inefficient procurement policy, on Jan. 28, 2020, a Decree issued by the Ministry of Health was published in the Official Gazette of the Federation, by means of which the requirements and evaluation procedures of the following regulatory authorities were recognized as equivalent to the regulatory requirements of our domestic legislation: Swiss Agency for Therapeutic Products-Swissmed, European Commission, US Food and Drug Administration, Canada Ministry of Health, Administration of Therapeutic Products of Australia, Reference Regulatory Agencies PAHO/WHO; prequalified by the Prequalification Program for Medicines and Vaccines of the World Health Organization or Regulatory Agencies members of the Pharmaceutical Inspection Cooperation Scheme, which was modified in 2021, the purpose of which was to allow the importation into Mexico of health supplies with and without marketing authorization, having to start the registration process with the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) within a period of 10 days in order to be considered in subsequent imports under said scheme.

In this regard, the Ministry of Health established that the importation of medicines without marketing authorization will be possible in those cases of “need for the correct and timely provision of health services,” and that said authority will coordinate to determine the importation of those “necessary” medicines.

This agreement was questioned because the specific circumstances that should be updated to consider that we are in a state of extraordinary “need” that requires the importation of foreign medicines without having been previously subjected to the evaluation and analysis process required by COFEPRIS to be able to verify that said medicines comply with the quality, safety and efficacy requirements in the terms provided for in the General Health Law, the Health Supplies Regulation, Mexican Official Standards and other applicable regulatory devices were not established, and in the same way, the supposed “legal instruments” according to which the Ministry of Health must coordinate to determine the importation of those “necessary” medicines were not specified, ignoring the observance of intellectual property rights.

These agreements were applied indiscriminately for four years by various institutions of the health sector in public tenders and thanks to them, the entry into our country of some substandard medicines was allowed, sometimes without having submitted their application for sanitary

registration to COFEPRIS within the 10 days referred to in said Decree. In other cases, the supplied medicines infringed patent rights and protection of clinical test data.

This scheme of importing supplies from abroad without marketing authorization was left without effect by the same Ministry of Health through a Decree published in the Official Gazette of the Federation on Sept. 11, 2024, considering that it is no longer necessary to have said scheme of recognition of equivalent regulation.

However, almost four months later, the Ministry of Health issued the "Decree to obtain the import permit for health supplies intended to guarantee the supply of the public sector," which was published on Dec. 4, 2024, in the Official Gazette of the Federation and which came into force the following day, which again allows granting import permits for medicines and medical devices, with the exception of psychotropic drugs, narcotics, and vaccines that do not have a marketing authorization granted by COFEPRIS to those applicants who have marketing authorizations or health registrations issued by regulatory authorities of countries such as the United States, Canada, the United Kingdom, France, Switzerland, and Japan, among others, so that they can participate in consolidated public tenders for the health system in Mexico, repeating the obligation to request the marketing authorization within a period of 10 days before COFEPRIS, once the import permit is obtained.

The justification for the measure, according to the authority that issued it, is to guarantee timely access to health supplies, simplifying the regulatory requirements that allow the Mexican state to have the best contracting conditions with guarantees of safety, quality, efficacy and performance.

This new Decree responds to the same problem of a deficient medicine supply policy that has not been overcome and that ignores the obligation to adequately observe our regulatory and intellectual property framework.

Indeed, the right to health, in addition to implying the right of individuals to enjoy the highest possible level of physical and mental health, also implies the right of access and availability to medicines in order to achieve the enjoyment of that right, which must be of quality in all its forms and levels; hence the need to implement laws, regulations and other normative provisions that allow ensuring the quality, safety, and efficacy of medicines prior to their manufacture, marketing, and supply, since this is a way to guarantee the enjoyment of the right to health protection of the population.

However, this Decree appears to contradict the implementation and observance of quality, safety and efficacy standards for equivalent medicines, granting them an administrative benefit that will result in the lack of timely compliance with our regulatory framework. Likewise, said Decree also fails to comply with intellectual property rights, since it ignored the provisions of articles 168 of the Federal Law for the Protection of Industrial Property, 167 bis of the Health Supplies Regulation, as well as the provisions of articles 20.48 of the Treaty between Mexico, the United States, and Canada (USMCA) and article 39, paragraph 3 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), since it fails to expressly establish the procedure and specific measures that the Ministry of Health, in coordination with COFEPRIS, will implement prior to the importation of medicines that do not have marketing authorization to guarantee due observance and recognition of clinical data related to the safety and efficacy of reference and innovative medicines previously authorized by the health authority in our country. According to these international treaties, the protection of clinical data refers to the obligation of the parties to these international instruments to protect information related to the safety and efficacy of a medicine that uses new chemical components, which has been submitted to health authorities as a condition for approving its commercialization, against all unfair commercial use and disclosure, when obtaining it has involved a considerable effort.

Likewise, this Agreement also fails to establish the prerogative of patent holders to exclusively exploit them, in relation to the linkage system established in articles 162 of the Federal Law for the Protection of Industrial Property, 47bis of the Regulation of the Industrial Property Law, article 167 Bis of the Health Supplies Regulation and the International Treaties to which Mexico is a party, since through these the importation of medicines without marketing authorization granted in Mexico is permitted.

In my opinion, this new Decree suffers from the same defects as the previous ones in an effort to provide the bidding authorities with a greater number of options for medicines and medical devices without adequate planning and a public procurement policy, rendering the observance of the linkage system that exists between patents and marketing authorization of medicines and the protection of clinical data void.

Photo by: Armando Arenas