Expert Contributor

Measures Needed to Counter Entry of Unauthorized Medicines.

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The shortage of medicines and the facilities provided by e-commerce have increased the sale of medicines that come from abroad, mainly through websites that offer them in Mexico from anywhere in the world, regularly at lower prices than in our country and distributed through parcel and courier services.

Although the the medicine may be considered a product manufactured by a subsidiary company of the holder of the marketing authorization in Mexico or any other non related company, these medicines do not have a marketing authorization granted by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), since they have not gone through the regulatory process established in our legislation to prove their quality, safety and efficacy.

The introduction of these medicines into national territory is clearly illegal . At the time of their entry into the country, the sanitary conditions under which they are entered, transported and distributed are unknown. Also unknown is whether the products have been subjected to review and control by appropriate and authorized sanitary facilities. In addition to that, there is no certainty that they will be subject to sanitary controls by an authorized party to guarantee proper quality.

Having not complied with the regulatory framework of our country due to the lack of a marketing authorization, it is evident that they also do not have an adequate pharmacovigilance plan or quality management system, which prevents health professionals and the pharmaceutical companies themselves from providing proper follow-up regarding pharmacovigilance, since the detection and analysis of possible risks derived from the use of medicines in humans are challenging.

The foregoing, without considering that the labels and instructions for use are written in a language other than Spanish and it is not certain if the expiration date is at least 12 months, as established by the health law for medicines from abroad, are factors that result in inadequate supply for patients.

These medicines enter our country in various ways, typically through import permits granted by COFEPRIS, with the help of companies that obtain them through a network of people who request the drugs for "personal use." This falls under the exception outlined in article 132 of the Health Supplies Regulation, which establishes that the authority may grant an import permit for finished products that do not have a marketing authorization, only in the following cases: (I) when any contingency occurs; (II) when required by health policy; (III) for purposes of scientific research, registration or personal use, or (IV) for laboratory tests.

However, several medicines offered, commercialized and distributed in Mexico have been detected to which none of the exceptions in the aforementioned article would apply. That is, they are introduced into Mexico without observing our regulatory framework to the detriment of the pharmaceutical industry that does comply with health regulations. This constitutes a potential risk to the health of those who consume them.

This phenomenon has increased during the last four years, despite the fact that the pharmaceutical industry in Mexico has consistently denounced this situation before COFEPRIS; however, until now, the results have been scarce, due to the fact that despite the importation and commercialization of such drugs contravenings health regulations, the health and customs authorities have not made a significant effort to prevent and eliminate these potential health risks.

As a result, health complaints are accumulating atCOFEPRIS, which is faced with the large number of medicines from abroad that are circulating in our country, as well as medicines that, despite having a marketing authorization, are sold on the black market, which together represents a serious health risk.

For this reason, preventive work is necessary, including collaboration among all the actors in the pharmaceutical industry, chambers and associations, as well as the health and administrative authorities at different levels of government, such as the National Customs Agency, the Mexican Institute of Industrial Property, the Attorney General of the Republic and the Federal Consumer Attorney's Office. This will allow the problem and its complexity to be analyzed, exchanging the available information in order to implement detection mechanisms and inhibit these schemes that introduce medicines from abroad that do not have a marketing authorization.

On the other hand, an effective and agile investigation of the information provided in health complaints is also essential, regarding the scheme for selling medicines through electronic media

and distributed through courier services. Evidence must be collected to issue sanitary alerts with the best possible information for the benefit of the population. As well, the import permits granted by COFEPRIS must be carefully analyzed, with the issuance of security measures that are effective against offenders.

These measures will provide certainty to both the general population and the pharmaceutical industry regarding the origin of their pharmaceutical products, which will allow us to strengthen our regulatory framework.

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