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Do New Medicine Procurement Rules Violate Constitution?

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Within the framework of the agreement that the Health Institute for Welfare (INSABI) signed with the UN Office for Project Services (UNOPS) for the procurement of medicines for the public sector in order to be able to carry out mega tenders in Mexico, the addition of the fifth paragraph of article 1 of the Law of Acquisitions, Leases and Services of the Public Sector (Acquisitions Law) was published in the Official Gazette of the Federation. The objective, according to its supporter, was to combat corruption and generate savings for the government through the acquisition of medicines in Mexico and abroad with the intervention of international organizations without the need to abide by the rules and conditions established in the procurement law.

The controversial addition to the regulatory law of article 134 of the Constitution, verbatim establishes the following:

> "The acquisition of goods or provision of health services contracted by agencies and/or entities with international intergovernmental organizations, through previously established collaboration mechanisms, is exempted from the application of this Law, provided that the application of the principles set forth in the Political Constitution of the United Mexican States is demonstrated." This exception, which allows the health sector authorities to not apply the Acquisitions Law in the procurement of goods and services through international intergovernmental organizations such as UNOPS, has generated great concern in the pharmaceutical industry in Mexico. There is uncertainty about the bidding process itself, and therefore, compliance with our legal framework. Although there are many legal inconsistencies that we will not touch because they exceed the scope of this article, I will focus on the most notorious, such as the clear contradiction with the federal Constitution, noncompliance with certain international commitments, the lack of a mechanism to verify compliance with regulatory standards, as well as the lack of observance of the legislation on intellectual property, so that it is expected that both the bidding process and the awards made by UNOPS will not be exempt from claims before the courts in Mexico.

Here are some of the most egregious inconsistencies in the fifth paragraph of article 1 of the Acquisitions Law:

Article 134 of our Constitution establishes the following:

> “Procurements, leases and disposals of all types of goods, provision of services of any nature and the contracting of works that they carry out, will be awarded or carried out through public tenders by public call so that solvent proposals are freely presented in a closed envelope, which will be open publicly, in order to ensure the State, the best available conditions in terms of price, quality, financing, opportunity and other pertinent circumstances.”

If the constitutional rule establishes that public sector acquisitions must be carried out through public tenders or awards for all type of goods and services of any nature, the exception of applying the law itself that regulates article 134 of the Constitution clearly contradicts the constitutional standard because it does not establish that its application can be restricted in the case of the acquisition of goods and services for health. That is, this new provision unduly excludes a single sector of the industry: the providers of services and goods for health.

On the other hand, this provision orders that the procurement of medicines with international organizations must be done through previously established collaboration mechanisms, provided that the application of the principles established in the Political Constitution of the United Mexican States is demonstrated; however, this new provision does not establish what these collaboration mechanisms are or their scope, which causes legal uncertainty in the sector, since Article 134 of the Constitution does not authorize the procurement of goods and services by the state to be carried out through previously established collaboration mechanisms, which in this particular case is an agreement entered into between the Mexican government through INSABI and UNOPS, whose contract terms are outside the law and their conditions are not part of our legal framework.

That is, when the conditions are not suitable for the government, Article 134 of the Constitution itself provides that the bases, procedures, rules, requirements and other elements must be established to prove the economy, effectiveness, efficiency, impartiality and honesty that also ensure the best conditions for the state, which is not seen in this new provision for government purchases. In my opinion, the application of the principles set forth in the Constitution, as established by the addition to article 1 of the Acquisitions Law, could not be proven.

On the other hand, this addition would be questioned regarding compliance with Article 4 of the Constitution, since it deprives the state of compliance with the obligation to guarantee the provision of quality health services, because it allows the acquisition of medicines from foreign sources without having been evaluated and approved by the country's health authorities regarding safety, quality and efficacy, since it lacks a verification mechanism of these regulatory standards that are contemplated in domestic legislation.

Another aspect of great concern for the pharmaceutical sector is the lack of observance of the exclusive patent rights provided for in Article 28 of the Constitution. The patents in force protect active principles, pharmaceutical formulations and medical uses published by the Mexican Institute of Industrial Property (IMPI) in the Gazette of Patents in Force for Medicines. Under the previous conditions, these would be observed as part of the mechanism to prevent infringement of patent rights, known as the linking system, which now may not be taken into consideration or perhaps only partially for some types of patents, such as those of active principle, allowing awards to companies that could offer a generic medicine still protected by patent in Mexico, since this provision does not

contain this obligation, in addition to the ignorance of UNOPS of our legal framework.

Likewise, this new regulation fails to observe the provisions of articles 20.48 of the Agreement between Mexico, the United States and Canada (USMCA) (previously articles 1711 subsections 5. and 6. of the North American Free Trade Agreement (NAFTA)) and Article 39 subsection 3 of the Agreement of the World Trade Organization on Trade-related Aspects of Intellectual Property Rights (TRIPS), since this regulation fails to expressly establish the measures that the authority, and even UNOPS, must observe to guarantee the due protection of the test data related to the safety and efficacy of the reference and innovative medicines previously authorized by the health authority in Mexico.

This new provision, in addition to contradicting the guiding principles of the Constitution regarding public procurement, lacks regulatory coherence, which in itself would also violate the USMCA, since these new procurement policies are clearly incompatible with our legal framework. Likewise, the reasons for which it was decreed are unjustified and discriminatory in our country's health sector; in fact, the text originally proposed by the legislator, although with certain deficiencies that could well be corrected, intended to comply with said principles, according to the following text:

> "In the case of the procurement of goods or provision of health services, when the market investigation concludes that the tender is not the ideal way to ensure the State the best conditions in accordance with the provisions of Article 134 of the Political Constitution of the United Mexican States, agencies and entities, prior authorization of the Secretariat through the Mayor's Office, may contract with international intergovernmental organizations through the collaboration mechanisms previously established with them, subject to the rules and regulations and procedures that govern them."

In short, these new rules represent a great challenge for all participants in the health sector in Mexico. The complexity of this mega-tender anticipates that errors will be made in respect of rights and compliance with regulatory standards, delivery of medicines, and distribution, whose questions have not been fully resolved. Although it seems that the bidding process is advancing as of the date of this writing, the reality is that it is expected that in the face of such uncertainty, the scope of discretion will be a source of lawsuits and the judiciary will have in its hands the definition of its constitutionality.

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