Mexico's New Healthcare Procurement Model: Promise or Pitfall?

Ingrid Ortiz, a senior associate at OLIVARES law firm, examines one of the most significant medicine procurement transformations in Mexico's history. In response to chronic drug shortages and inefficiencies in public health product distribution, President Claudia Sheinbaum has introduced a New Consolidated Model for the Procurement of Health Products and Medical Supplies for 2025-2026. What impact will this model have on supply security, as well as competition, regulatory oversight, and patient safety?

The healthcare system in Mexico has become one of the most critical issues on the country's political agenda. In particular, the supply of health products has become an urgent and fundamental need within the public healthcare sector, where the lack of these supplies shows severe repercussions that directly affect the exercise of the human right to health for the Mexican population.

For the above, and to ensure the supply of health products in public healthcare institutions, the President of Mexico, Claudia Sheinbaum, announced a New Consolidated Model for the Procurement of Health products and Medical Supplies for the 2025-2026 period on October 31, 2024. This initiative will be led by the Ministry of Health and the Laboratories of Biologics and Reagents of Mexico, S.A. de C.V. (BIRMEX).

This new model, which involves an investment of 130 billion pesos (USD 6.34 billion), has been described as one of the most ambitious public procurement procedures in the country's history. It includes both generic and patented health products. With the inclusion of both national and international suppliers, and the addition of 4,454 drug and medical supply codes, with volumes estimated at 4.934 billion units, calculated to meet the needs for the next two years, this framework aims to ensure the availability of health products within the National Health System for Well-being.

However, beyond its scale, this new consolidated procurement model incorporates, for the first time, a public discussion strategy based on transparency and participation. To this end, the platform "Public Dissemination and Discussion of Consolidated Procurement of Health products and Medical Supplies in the Health Sector" was created, allowing anyone to consult and provide comments or suggestions on the technical conditions and other guidelines, as well as stay informed on the development of the stages of the procurement process.

In this regard, a final report presented by the Ministry of Health and BIRMEX revealed that the website received 53,000 visits and 3,716 comments and suggestions. It is important to note that these comments were not binding, but they were considered in defining the technical annexes and guidelines for the consolidated procurement.

In parallel with the consolidated procurement, on December 4, 2024, the "AGREEMENT to Obtain the Import Permit for Health Supplies Intended to Ensure the Supply of the Public Sector" was published in the Federal Official Gazette. This agreement allows the importation of health supplies into Mexico that have a sanitary authorization issued by regulatory authorities in specific countries listed in the agreement, aimed at supporting the consolidated procurement by BIRMEX and the Ministry of Health.

As this decree could provide some benefits to the Public Healthcare system, it is worth mentioning that the industry has shown some concern as this agreement contains some loops that may result in unfortunate application or oversights of the applicable legislation on force. Mexico has already experience with decrees with similar provisions and objectives, which allowed the issuance of an import permits without a justifiable cause, cases where the product or the therapeutic option were duly authorized by the Mexican Sanitary Agency, the Federal Commission of Protection against Sanitary Risks, COFEPRIS (imposing an additional burden in comparation to companies favored by the decrees), also available in the country, and in some cases with exclusive rights granted (i.e. patents and others) being rejected for a product that may never be evaluated by COFEPRIS, despite the requirements provided in such decrees, since the companies would often fail to file the corresponding Marketing Authorization application and would not no go through a linkage system to prevent rights infringement.

In other words, this new decree was welcomed by some participants, yet it has been carefully analyzed by others as well as rejected. The main concern lies in matters of safety, efficacy, and quality of the products primarily, as well as the risk of ignoring previous rights granted (i.e. marketing authorizations, patents, etc.). and granting an unjustified competitive advantage to foreign entities, falling in violation of the applicable legislation. Also, there were doubts on the role that would be played by this decree within the public tender ongoing until the first weeks of January 2025.

Initially, it was stated that the tender call would be published on December 2, 2024, with the award decision to be made on December 17 of the same month. Due to changes in its format, the new date was set for December 10, with the award decision scheduled for December 26. However, the tender was eventually published on December 13, and the award decision was scheduled for January 4. This date was once again rescheduled to January 13, 2025, the day when the final award record will be available.

Correspondingly, it was initially stated that 4,454 product codes would be tendered, a number that was later reduced to 3,900. Proposals were received for 98.5% of these, and 348 were negotiated through single-source and patent negotiations. To cover the remaining 1.5% of items, a second round of bidding will begin on January 17, 2025.

While finishing this article, we were able to find out some of the results within the tender, and they were indeed surprising, as some of the companies participating in such tender went through a very novel process and received unusual responses to their proposals, which ended up with thoughtful discussions and evaluations on the next steps for the participants. On the other hand, after issuing the decisions on this tender BIRMEX has been supportive and seems to be looking for better results in upcoming proceedings.

In brief, as it was a new model of acquisition of health products, BIRMEX and the participants worked hard to achieve the best results in this tender. Nevertheless, a matter of trial and error was observed in these weeks, as it was an international and open tender, in addition to the decree foreign companies without having an MA dully granted in México were allowed to participate, yet in some cases the lack of MA was considered in the final decision dismissing such proposals; there was a lot of uncertainty on the evaluation of proposals that involved a patented product despite that the Law and its regulations are clear that such rights must be observed and that the acquiring authority does not need to conduct a tender but can chose a direct acquisition; also the “lack” of documentation played a decisive part despite the fact that such documentation requirements were not applicable for some specific cases.

So far, it seems that BIRMEX is still working to address some of these issues and achieve a positive outcome for the system, hopefully the matters that caused doubt and raised some complaints among the participants and the authority itself will be overcome soon, and within the next processes of this kind. In the meantime, all the parties involved should continue working on suitable strategies to ultimately adjust to these new models of acquisition of health products aiming to ensure legal certainty and the proper observance of exclusive rights, to duly provide access to safe, effective and quality medicines and health products to the Mexican patients.

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