

Guidelines for the Promotion of National Investment in the Pharmaceutical Industry

Mexico City, May 25, 2026

On May 21, 2026, the “Guidelines for the Promotion of Investment in Mexico in the Production of Medicines, Health Supplies and Medical Devices, or in the Development of Research and Development” (the “Guidelines”)¹ were published in the Federal Official Gazette.

The Guidelines apply exclusively to the public procurement of generic medicines, health supplies and medical devices, and are mandatory for *Laboratorios de Biológicos y Reactivos de México, S.A. de C.V.* (“Birmex”), the Institute for Social Security and Services for State Workers (ISSSTE), the Mexican Social Security Institute (IMSS), the Health Services of the Mexican Social Security Institute for Wellbeing (IMSS-Bienestar), the National Health Institutes, the Federal Reference Hospitals, and any other institutions providing health services that participate in consolidated procurement procedures for generic medicines, health supplies and medical devices.

The Guidelines do not apply to procurement procedures for generic medicines, health supplies and medical devices that are covered by treaties, to avoid conflict with international instruments currently in force and signed by Mexico that contain a government procurement chapter.

In consolidated procurement procedures for generic medicines, health supplies or generic medical devices, and in compliance with the provisions of the Acquisitions, Leases and Services of the Public Sector Law (“LAASSP”), its Regulations and the Guidelines, Birmex shall apply a points-and-percentages evaluation method. To this end, Birmex must obtain authorization from the Ministry of Anti-corruption and Good Governance and include, within the criteria used to evaluate a bidder’s capacity, those relating to Infrastructure, Production, and Research and Development, in accordance with the following:

- a. Infrastructure dimension: demonstrating investment within national territory in the production chain of medicines, health supplies and medical devices;

¹ The Guidelines are issued for the purpose of complying with the provisions of the “Decree promoting investment in national territory to strengthen the development of the pharmaceutical industry and the production of health supplies, as well as the development of national scientific research”, published in the DOF on June 2, 2025 (the “Decree”).

- b. Production process dimension: demonstrating the performance of substantive stages of the value chain within the country, from the manufacture of active pharmaceutical ingredients to the finished product; and
- c. Research and development dimension: demonstrating the development of scientific research or innovative health products.

Compliance with the foregoing shall be evidenced by means of specific documentation, including sanitary licenses (for factory, laboratory or warehouse); the notice of the designated responsible sanitary person; a valid Good Manufacturing Practices Certificate; registration of the investment project with the Ministry of Economy; or binding contracts for infrastructure development, among others.

The Guidelines entered into force on May 22, 2026, and shall apply to procurement procedures for medicines, health supplies, and medical devices scheduled for delivery from 2027 onwards.

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