January, 2016

GOVERNMENT AMENDMENTS FOR THE PHARMACEUTICAL BILL II

On January 4th, 2016, the President of the Republic introduced a series of amendments to the bill of law that, "modifies the Health Code in order to regulate generic bioequivalent pharmaceutical products and prevent the vertical integration of pharmaceutical laboratories and pharmacies", – Bill No. 9914-11- ("Pharmaceutical Bill II").

This Government intervention has broadened the original scope of the project, and should also accelerate its discussion, even though the congressional discussion period has not yet occurred in either the Senate or in the Representatives Chamber.

The central elements of the amendments introduced by the Government are:

1 It establishes the obligation to report to the Ministry of Health, the Public Health Institute, and the Central Procurement Agency about the voluntary suspension of pharmaceutical products, as well as any other circumstance that puts the supply of a product at risk.

2 It is established that pharmaceutical companies that either manufacture or import their products must provide the Ministry of Health and the Public Health Institute with information about the prices of the pharmaceutical products that are available for sale , as it is determined by the regulation that will be enacted for this purpose.

3 In prescriptions, the pharmaceutical product must be identified by its International Non-proprietary Name (INN), however, it is permitted to also include the commercial name.

4 The administrative appeal before the Ministry of Health against actions and decisions taken by the Director of the Public Health Institute is eliminated.

5 The Ministry of Health, the Regional Secretaries of Health, and the Public Health Institute will have the ability to make administrative interpretations of the rules that are within their scope, and these interpretations will be overarching and mandatory.

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6 The statute of limitations for violations of health regulations and administrative sanctions is extended to 4 years. Furthermore, a new regulation for the health investigation procedure will be enacted.

7 The ability of the Ministry of Health to issue an opinion on the matter of the cancelation of the health registry of a pharmaceutical product is eliminated.

8 Article 128 of the Sanitary Code is introduced, which establishes that the importation of pharmaceutical specialty products may be performed by pharmaceutical laboratories, pharmacies, drugstores, pharmaceutical warehouses and, in general, by any natural person or legal entity, according to the applicable legislation.

9 The power of the Public Health Institute to authorize the installation of pharmacies and pharmaceutical warehouses is eliminated, transferring that power to the Regional Secretaries of the Ministry of Health.

10 The enactment of a new policy for therapeutic equivalence is entrusted to the Ministry of Health, including a new Technical Regulation that determines the active pharmaceutical ingredients that must demonstrate therapeutic equivalence.