NEWSLETTER REGARDING THE NATIONAL PHARMACEUTICAL ACT

January, 2014

The National Pharmaceutical Act was enacted January 7, 2014. This law modifies the Chilean Sanitary Code in many aspects which concern the promotion and conditions of commercialization and dispensation of pharmaceutical products. The main issues regulated by this Act are:

1 ***Prescriptions with declaration of INN:*** The new legislation compels the professionals authorized to prescribe drugs to individualize in the prescription the pharmaceutical product with its trade name, adding, for information purposes, its International Non-proprietary Name (INN, in case there is a duly certified bioequivalent product), which will authorize its exchange. The bioequivalent product must have demonstrated such condition according to the requirements included in the respective supreme decree issued through the Ministry of Health, which shall adjust to the regulations of the World Health Organization.

2 ***Interchangeability of Bioequivalent Medicines:*** The law provides that in cases where a medicine that shall demonstrate bioequivalence has been prescribed, the Pharmacist, at the patient's request, may dispense any bioequivalent product, as long as such qualification has been demonstrated according to the requirements specified in paragraph 1, above. Additionally, it compels the distribution establishments to have a list of the products that must prove being bioequivalents.

3 ***Dispensing in Unitary Doses:*** The law contemplates the possibility of dispensing pharmaceutical products in unitary doses, which implies the division of the package in doses different to the one originally contained. Dispensation through unitary doses is authorized and can be executed in pharmacies in accordance with the prescription. The Technical Director of the pharmacy will be responsible for the dispensation in unitary doses and fulfilling the medical prescription. However, the issuance of a Decree to control the procedures and conditions regarding the safety and the identification of the product, patient and prescriber on the product's label once dispensed in unitary doses is still pending.

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4 ***On-Shelf Commercialization of OTC Products:*** OTC products may be available in pharmacies and pharmaceutical stores over the counter, allowing direct access by the public, as long as it is warned through infographics, about its adequate use and dosage. A regulation will be issued defining the conditions of conservation, storage, public information and safety measures to avoid risks associated with this new selling method.

5 ***Information about prices:*** Suppliers of pharmaceutical products, including pharmaceutical laboratories, importers or distributors, shall publish their selling prices and their mechanisms for discounts per volume. Additionally, any conduct that is considered to be an arbitrary discrimination in the commercialization of pharmaceutical products will be sanctioned.

6 ***Prices in product´s packages:*** The new legislation compels pharmacies and other authorized establishments to dispense pharmaceutical products with the information of their price in a clear, opportunely and verifiable way. This is meant to guarantee transparency, access to information and veracity of the drug.

7 ***Incentive to professionals:*** The donation of pharmaceutical products for the purpose of advertising is prohibited. Economic incentives of any kind which benefit the professionals authorized to prescribe and dispense pharmaceutical products are also prohibited, aligning the criteria with the provision contained in article 213 of the S.D. 03/2010.

8 ***Limiting Information to only the Professional:*** The promotion of pharmaceutical products aimed to professionals authorized to prescribe them shall not be made through social media intended for the general public.

9 ***Limits on the donation of pharmaceutical products:*** The donation of pharmaceutical products to non-profit assistance establishments is allowed, as long as those products are included in the National Formulary of Medicines, elaborated by the Ministry of Health.

10 ***Special requirements for pharmaceutical products´packages:*** Pharmaceutical products shall be presented in packages that make it difficult for a child (without the assistance of an adult) to ingest, and shall not be shaped as any kind of candy or toy, or any other form that promotes their consuming, according to a Regulation that will be issued in the future regarding this matter.