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PUBLIC HEALTH INSTITUTE APPROVES NEW TECHNICAL GUIDE FOR SANITARY REGISTRATION OF ALLERGENS

On February 20 of this year, the Public Health Institute (hereinafter "ISP"), approved through Exempt Resolution No. 401/23 the technical guide for the sanitary registration of allergens with the purpose of establishing the guidelines and requirements for the sanitary registration of these products (the "Guide").

Firstly, it is noted that globally there are difficulties for their registration in the regulatory agencies, given the complexity in demonstrating their efficacy and safety by means of pre-clinical and conventional clinical studies. For this reason, it was concluded that there is a gap in terms of the sufficiency of criteria and requirements for obtaining their registration.

Additionally, in Chile, most of the allergen products for in vivo diagnoses and treatments have been used without sanitary registration and have entered the country through resolutions of authorization of exceptional imports and by means of medical prescription for personal use, which the authority has attributed to the lack of specific guidelines for this type of drugs, which is indeed a regulatory gap.

The Guide, after quoting certain international regulatory background, notes the use of allergens in Chile and their current situation, especially in relation to their administration. Subsequently, the following guidelines are established for the registration of allergens in Chile:

• First, the ISP addresses the regulations established for the registration of drugs in Chile, since allergens are considered as such, in Supreme Decree No. 03/2010 Regulation of the National Control System of Pharmaceutical Products for Human Use ("D.S. 03/2010"). In this regard, it refers to the types of registration procedures indicating that the ordinary system will be the procedure by which this class of products must be registered.
• Second, specific quality requirements are established, referring to

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the presentation format of the registration, especially in format modules 3, 4 and 5, noting certain items such as the active ingredient and the finished product.Regarding the active ingredient, certain differences applicable to the registration of allergens are identified in its general information, manufacturing process, characterization of the active substance and its limits, controls, reference standards and stability.

Regarding the finished product, the differences identified refer to the description and composition, manufacturing process controls, finished product controls, reference standards and stability of the product.

• Subsequently, specific efficacy and safety requirements are established. In this section, guidelines are established regarding pre-clinical information, toxicology, safety and efficacy history.
• Finally, homologous groups are listed, with the understanding that allergen extracts prepared or from different species, genders or families and finished products derived from them can be grouped together. To complement this section, the European guide "Guidelines on Allergen Products: Production and Quality Issues" is included, which contains an annex of homologous groups that are used as a basis and is transcribed as a proposal.

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