/Carey

February 28, 2023

LEGAL ALERT

Public Health Institute approves new guide for sanitary registration of homeopathic pharmaceutical products

On February 20 of this year, the Public Health Institute (hereinafter "ISP"), approved through Exempt Resolution No. 405/23 the technical guide on homeopathic products with the purpose of providing the guidelines and requirements for the request of the sanitary registration of these pharmaceutical products in order to provide complete and updated information that supports the quality, safety and efficacy of these products (the "Guide").

In this regard, it is expected to regulate and guide those who apply for the sanitary registration of these products about the information required to make the application and facilitate its correct presentation. The above, considering the particularities of this kind of products which, according to the Guide, cannot be treated in a similar way to those pharmaceutical specialties of chemical synthesis.

After a brief description of homeopathy and its origins, the Guide extends to the concept of homeotherapy and defines homeopathic medicines. In this regard, it notes that a medicine is considered homeopathic only when it is prepared with homeopathic raw materials, according to homeopathic preparation methods described in official pharmacopoeias or other reference texts.

Additionally, after quoting the international regulations, the regulations and presentation of background information for the sanitary registration in Chile are established. Likewise, it includes clarifications regarding article 41° of Supreme Decree N°03/2010 Regulation of the National Control System of Pharmaceutical Products of Human Use, which addresses the requirements for the sanitary registration of this class of products. The precisions extend mainly to:

- The pharmaceutical quality background of the product
- The presentation of background information supporting its efficacy and safety.

- Indicates that there are two registry procedures, ordinary and simplified, and points out the requirements to benefit from the simplified procedure
- Safety and efficacy

It is noted that the background information for the application for registration must be submitted in accordance with the format approved by the ISP (CTD format), which is organized in five modules in general, noting the fact that the Guide specifies the requirements for each module in the case f homeopathic pharmaceutical products.

Authors: Guillermo Carey; Ignacio Gillmore; Alejandra Del Rio; Javiera Péndola; Emilia Corbo