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PUBLIC HEALTH INSTITUTE APPROVES NEW GUIDELINE FOR THE PERFORMANCE OF POST-AUTHORIZATION SAFETY STUDIES ON PHARMACEUTICAL PRODUCTS

On February 14 of this year, the Public Health Institute ("ISP") approved -by means of Ex. Res. No. 369/2023- a new guideline regarding the performance of post-authorization safety studies of pharmaceutical products (the "Guideline").

This arises as an attempt to overcome the current regulatory gap caused by the lack of recommendations that provide concepts or technical guidelines allowing the development of this type of studies for registered products in Chile with well-defined therapeutic indications.

The purpose of this kind of studies is to confirm whether the benefit-risk profile of a given drug is still favorable for its distribution in the country. Therefore, the Guideline is the technical document, complementary and in line with the current regulations which allows the actors involved in the pharmacovigilance system to learn about the different strategies for the development of the studies and the implementation of the methodologies.

Additionally, with the Guideline, the ISP seeks to keep drug safety information up to date and to promote the incorporation of post-authorization studies for all types of human studies, contributing to the transparency of information through the publication of studies in progress and their results.

The Guideline provides recommendations for both interventional and non-interventional studies –with particular emphasis on the latter– and it is addressed, generally, to all those who participate in safety research in the post-authorization phase, including sanitary registration holders and universities.

It is important to emphasize that the Guideline refers to post-authorization safety studies of pharmaceutical products registered in Chile and not to Phase I, II, III and/or preclinical clinical

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safety studies, nor to clinical studies to explore new indications, new age groups, associations, dosages, etc.

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