COMMUNICATION N° 003 -2026-DIIS/INS

Publication date: July 24, 2026

CLARIFICATIONS REGARDING THE INFORMATION CONTAINED ON THE LABEL IMMEDIATE IN RESEARCH PRODUCTS

The Directorate of Health Research and Innovation of the National Institute of Health, within the scope of its responsibilities, and in accordance with the information provided by the General Directorate of Medicines, Supplies and Drugs is the line agency of the Ministry of Health (DIGEMID) through Official Letter No. 1505-2026-DIGEMID-DG-DPF/MINSA, communicates the following:

That, within the framework of the development of a Clinical Trial, the Clinical Trials Regulation (DS No. 021-2017-SA), prescribes in the second paragraph of its article 91 that, *"the immediate labeling of products under investigation must contain the following information: Product name, concentration of the active ingredient, route of administration, name of the manufacturer or logo, batch number and expiration date";*

In this regard, it should be mentioned that, in relation to the information contained in the immediate labeling, in cases where, due to its size, it cannot contain all the information required in article 91 of the REC, it must include at least: a) Name or code of the product, b) Concentration of the active ingredient, c) Route of administration, d) Batch number or identification code (Double Blind Studies) and e) Expiration date.

The labeling must guarantee the integrity, identification and traceability of the product under investigation during its storage, distribution, dispensing and use, until its return or final disposal.

Subdirectorate of Clinical Trials (SUDEC)
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