RHTLaw Vietnam

ASEAN+ We know ASIA.

January 2024

FURTHER GUIDELINES ON DRUG LABELS AND INSTRUCTIONS FOR USE OF MEDICINE

The Ministry of Health ("**MOH**") recently adopted Circular No. 23/2023/TT-BYT ("**Circular 23**") which amends and supplements Circular No. 01/2018/TT-BYT dated 18 January 2018 governing the drug labelling ("**Circular 01**"). Circular 23 becomes effective on 15 January 2024.

Drug labelling exception

It may not be required to have labels and instructions for use affixed to the drug packaging of radioactive drugs or drugs used in certain emergency cases. Instead, they can be attached to drug delivery documents or affixed to packaging used for the purpose of storage or transportation on case-by-case basis.

Specific timeline for supplementing auxiliary labels or the Vietnamese instructions for use applicable to the imported drugs

It may be required to add auxiliary labels or the instructions for use in Vietnamese ***after the custom clearance*** and ***before the release for circulation*** when the original labels or the Vietnamese instructions of use lack contents compared to those approved by the Ministry of Health or there have not been the Vietnamese instructions of use, as the case may be.

Required contents of labels

It is required to properly indicate on labels, as the case may be, full name and content, mass or concentrations of ingredients in the recipes, term of use, barcode, QR code, and others.

Transition period

Drugs or drug ingredients manufactured or imported before 1 January 2025 may use label samples or the instructions for use approved by the Ministry of Health until their expiry dates.

Labels or the instructions for use, which are attached to the applications for granting, renewing, amending or supplementing circulation registration certificates submitted to the authority before 15 January 2024 and being processed, may follow the regulations prevailing at the time of submission. However, the applicants are still encouraged to comply with this new Circular 23.

About the Authors

Benjamin Yap (Mr.)

Senior Partner
Ho Chi Minh City Office
Tel. (+84) 28 3820 6448

benjamin.yap@rhtlaw.com.vn

Dang Thi Tuong Vi (Ms.)

Partner
Ho Chi Minh City Office Tel.
(+84) 28 3820 6448

vi.dang@rhtlaw.com.vn

About RHTLaw Vietnam

>

RHTLaw Vietnam

Suite 1101, 11th Floor, Sofitel Central Plaza 17 LeDuan Boulevard, District 1, Ho Chi Minh City Vietnam

Tel: +84 28 38206 448

>

RHTLaw Vietnam – Hanoi Branch

Unit 1501B, 15th Floor, Charmvit Tower
117 Tran DuyHung Street, Cau Giay District, Hanoi Vietnam
Tel: + 84 24 3974 8881

RHTLaw Vietnam is a Vietnam law practice registered as a limited liability company in Vietnam (the "**LLC**").

It works in collaboration with the Singapore law practice RHTLaw Asia LLP. The LLC is a distinct legal entity in Vietnam.

Our model is driven by the focus on helping clients succeed, which translates to clear and precise solutions with high-level legal and commercial insights. We proactively grow our practice in tandem with regional and international fast-growing industries and areas like Banking & Finance, Capital Market, M&As, Inward & Outward Investment, Intellectual Property, Trading & Commerce, Real Estate & Construction, Telecommunications, Employment and Litigation

Find out more about us at www.rhtlaw.com.vn