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Review article

ANALYSIS AND IMPLEMENTATION APPROACHES: EVOLUTION OF VIETNAM'S REGULATIONS FOR LABELLING OF DRUG AND PHARMACEUTICAL PACKAGING GMP

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Abstract

To enhance drug quality, labelling transparency, and compliance with ASEAN standards, Vietnam has been continuously refining its regulatory framework under the guidance of its Ministry of Health (MOH). Circular 06/2016/TT-BYT in 2016 introduced many important changes to Vietnam drug labelling requirements, and Circular 02/2016/TT-BYT supplemented GMP standards on the packaging of medicinal products. We have reviewed these added regulatory requirements and how they differ from the existing 2008 guidelines. The study also provides execution methods to ensure easy compliance for local and foreign manufacturers, especially Indian exporters that account for a large share of pharmaceutical imports in Vietnam.

Keywords: Vietnam, Drug Labelling, GMP, Pharmaceutical Packaging, Regulatory Affairs, Implementation Strategy, ASEAN Harmonization

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Introduction

As one of the fastest growing pharmaceutical markets in South East Asia, Vietnam is projected to reach USD 10 billion by 2025 (1). Although domestic manufacturing capacity has been expanding, roughly 90% of medicines are still imported—emphasizing the need for effective regulation of products to ensure safety and quality.

Two landmark circulars were issued by Vietnam in 2016 to improve regulations and align to ASEAN practices including:

- **Circular 06/2016/TT-BYT** for Drug Labelling, replacing Circular 04/2008/TT-BYT.
- **Circular 02/2016/TT-BYT**, adding provisions to Article 9 of **Circular 14/2012/TT-BYT** (GMP for pharmaceutical packaging).

These established some new definitions, labelling content requirements, and implementation mechanisms that form the focus of this paper.

A comparative document analysis of the 2008 and 2016 Vietnamese MOH circulars is the ground for this study. Each updated requirement was examined for regulatory significance, practical implications, and alignment with ASEAN guidelines (2)(3)(4).

Amendments in Circular No. 06/2016/TT-BYT (Labelling of Drugs) (2)

The circular of 2016 changed the whole labelling guideline with specific updates to definitions, labelling content, layout, and responsibilities. The critical *new inclusions* are summarized below:

1. Expanded Definitions (Article 2)
New inclusions:

- Introduction of terms such as *"Original label"*, *"Auxiliary label" (secondary label in Vietnamese)*, and *"Commercial package"* to distinguish between packaging layers.
- Detailed definitions of *primary*, *secondary*, and *intermediate* packages—crucial for traceability and GMP compliance.
- New definitions for *batch number*, *instruction sheet*, and *registration number*, emphasizing traceability and documentation integrity.

2. Labels size, text colours, pictures and symbols on the labels (Article 5)
New inclusions:

- The text of all the compulsory information required on the label shall be of the minimum height 1.2 mm. The minimum text height is 0.9 mm for the secondary label.

3. Language Requirements (Article 6)
New inclusions:

- Compulsory information must be in Vietnamese, but product name, INN, and manufacturer's name can be in *foreign languages (English/Latin)*.
- Mandated secondary Vietnamese labels for imported drugs lacking full Vietnamese content, to be affixed in GMP or GSP-certified facilities before market release.

Impact:
These requirements promoted consumer safety and preventing misinterpretation of foreign labels by the foreign users. It also helps reduce the ambiguity for manufacturers during the preparation of dossiers.

4. Compulsory Label Contents (Articles 7–23)
New inclusions:

- **Mandatory details for labelling** of primary, secondary, and intermediate packages (viz., drug name, dosage form, batch number, expiry date, registration number, responsible entity, origin).
- It is not mandated to specify active ingredients and excipients for in vitro diagnostic reagents.
- For the manufacturer's name: An abbreviated name or business name in English is permitted given that the manufacturer is identified. If a drug has more than one manufacturer:
  - State each and every manufacturer of the marketed drug; or
  - State the manufacturer who is responsible for the batch release.
- The labels of ingredients classified as narcotic drugs, psychotropic drugs, or precursors must contain the text "Thuốc gây nghiện" ("narcotic drugs"), "Thuốc hướng tâm thần ("psychotropic drugs")", or "Tiền chất dùng làm thuốc" ("precursor") respectively.
- Adding sheet of instruction of PIL was made mandatory for all marketed drugs, written in Vietnamese, detailing usage, contraindications, adverse effects, and overdose management.
- New guideline for modern, oriental, and herbal medicines got introduced, incorporating both Vietnamese and Latin names for ingredients.

- Mandatory warnings added to labels: “Read instructions carefully before use” and “Keep out of reach of children”.
- Registration number shall be mentioned as text “Số Dăng ký” ("Registration number") or “SDK” and the number issued by the Ministry of Health. b). Import license number for imported drugs in Vietnam shall bear the text “Số giấy phép nhập khẩu” ("Import license number") or “GPNK” and the license number issued by a unit of the Ministry of Health.
- Batch number shall be expressed as “Số lô SX”, “Lô SX”, “LSX” or “SLSX” and information about the batch number. The information and composition of the batch number is decided by the manufacturer.
- The manufacturing date and expiry date shall be expressed in any of the following format: [dd/mm/yy], [dd. mm. yy], [dd-mm-yy], [dd mm yy], [ddmmyy].

Impact:
These updates have led from a minimal labelling to an alignment with a detailed comprehensive patient information and pharmacovigilance. The dual language requirement has helped improve the compliance with export requirements.

5. Prescription Symbol and Safety Notes (Article 24)
New inclusions:

- It is mandatory to display on the upper left corner the **“Rx” symbol** of secondary packages of prescription medicines.
- Warnings for external-use-only, injection routes, and child safety are now mandatory to be printed in bold letters.

6. Entity Responsibility (Article 25)
New inclusions:

- The label should bear a clearly stated name and address of the responsible entity—registrant, manufacturer, or importer.
- For contract manufacturing or franchise production, mandatory disclosure phrases like *“Manufactured under franchise of…”* or *“Manufactured by… under contract with…”* are required in Vietnamese language.

Impact:
This helped in improving the accountability and traceability— which was a critical part for GMP audits and regulatory implementation.

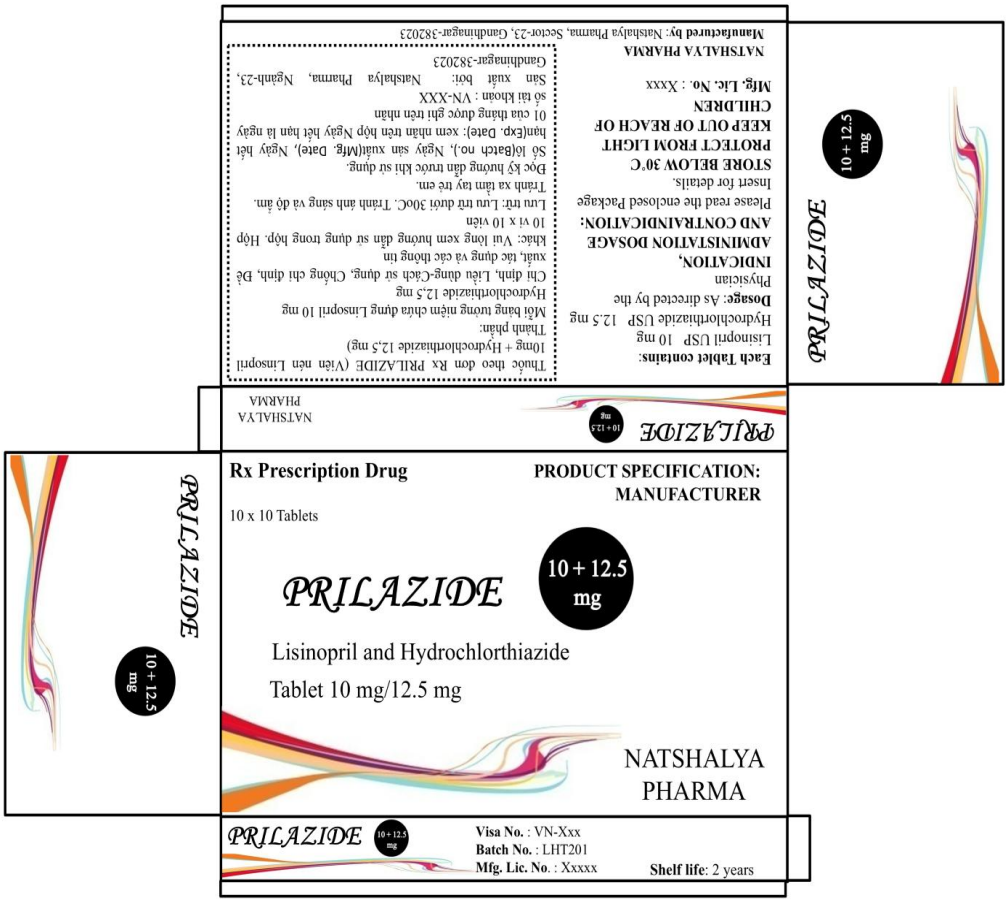

Figure 1

7. Drug Origin (Article 26)
New inclusions:

- Clear declaration of *"Manufactured in"* or *"Origin"* with the country name in Vietnamese or English.
- Distinction between country of manufacture and origin—essential for trade transparency and anti-counterfeiting.

8. Implementation and Transition (Final Section)
New inclusions:

- Circular 06/2016 replaced Circular 04/2008 with a **transition period**: existing registered drugs could continue using old labels until expiry.
- **Recommendation for early adoption** of new labelling rules before the July 2016 effective date.
- Requirement to **update labels via change registration** under Circular 44/2014 within 6 months of the new certificate issuance (5).
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Amendments in Circular 02/2016/TT-BYT (GMP for Pharmaceutical Packaging) (3)(6)

Amendments made in Article 9 of Circular 14/2012:

1. The packaging materials coming in direct contact with drugs has to go through a mandatory GMP compliance.
2. MOH to establish specific policies to promote GMP packaging adoption.
3. Only certified GMP packaging materials are made mandatory to be used by the drug manufacturers.
4. The Vietnam Pharmacopoeia Council and National Institutes of Drug Quality Control together will develop packaging quality standards.

Implementation Strategies

1. Gap Analysis: Compare existing labelling templates with the 2016 mandatory elements and secondary label structure.
2. GMP Alignment: Audit packaging vendors for GMP compliance and documentation readiness.
3. Local Translation Oversight: Engage certified Vietnamese translators and legal reviewers to ensure consistency of labelling terminology.
4. Regulatory Update Tracking: Maintain a version-controlled repository for all approved labels and instruction sheets.
5. Training: Conduct periodic workshops for QA/RA staff on updated definitions, Rx symbol placement, and bilingual labelling standards.
6. Pre-Approval Label Mock-ups: Submit bilingual artworks during registration to avoid post-approval discrepancies.

Conclusion

A significant change in the Vietnam's drug labelling regulations was introduced through the circular 06/2016/TT-BYT. A normal labelling regulation were now changed to a patient centric, traceable and harmonized regulation. The new requirements—definitions, bilingual language, marking the symbol Rx for prescription drugs, and instruction-sheet requirements— exhibit Vietnam's regulatory development and commitment to an alliance with the ASEAN regulations. A considerably strong pharmaceutical ecosystem has been developed in combination with the 2016 GMP addition for pharmaceutical packaging reforms.
A timely adoption to these updates shall ensure regulatory compliance, faster product approvals, and greater consumer trust for Indian and other foreign exporters.

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