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# CDSCO Notifies Clarification on Comprehensive Permission for Products Imported for Overprinting, Stickering, and Stamping under Rule 104A of the Drugs and Cosmetics Rules, 1945

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The Government of India, through the Directorate General of Health Services and the Central Drugs Standard Control Organization (Biological Division), has issued an Office Memorandum dated 26 May 2025, providing detailed clarification on the comprehensive permission for importing drugs for labelling, overprinting, and stickering under Rule 104A of the Drugs and Cosmetics Rules, 1945. This memorandum is a continuation of an earlier directive issued on 29 January 2020, aiming to address the specific requirements and conditions for such activities.

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## Introduction

The Drugs and Cosmetics Rules, 1945, specifically Rule 104A, prohibit the alteration, obliteration, or defacement of any inscription or mark made by the manufacturer on the container, label, or wrapper of any drug. However, this rule allows for alterations made at the instance, direction, or with the permission of the Licensing Authority. The recent Office Memorandum issued by the Drugs Controller General (India) seeks to provide further clarity on the conditions under which such alterations are permissible, particularly for imported drugs.

## Issuing Authority and Background

The Office Memorandum was issued by the Directorate General of Health Services, Central Drugs Standard Control Organization (Biological Division), under the Government of India. The Drugs Controller General (India) is the issuing authority, and the memorandum is dated 26 May 2025. This document builds upon an earlier Office Memorandum dated 29 January 2020, which initially outlined the permissions and conditions for labelling and overprinting activities. The need for this clarification arises from the necessity to ensure compliance with the Drugs and Cosmetics Rules, 1945, while enabling the import of drugs for specific labelling requirements.

## Provisions for Importing Drugs for Labelling

The memorandum clearly states that the activity of labelling, overprinting, or stickering is strictly allowed only for the import of drugs. Importers must hold a valid manufacturing license in their name to conduct these activities. This requirement ensures that only authorized entities can engage in the labelling process, thereby maintaining regulatory oversight and compliance.

## Facility and Personnel Requirements

The Licensee must have adequate facilities for storage, ancillary areas, and labelling. Additionally, the Licensee is required to appoint at least one manufacturing and QA personnel to the satisfaction of the SLA (State Licensing Authority). While a QC Laboratory and personnel may not be necessary for such labelling activities, the presence of qualified personnel ensures that the labelling process adheres to the required standards and regulations.

## Compliance with Current Provisions

The labelling process must comply with the current provisions of the Drugs and Cosmetics Rules. Importantly, the original label should not be concealed, and the License number and the activity carried out should be clearly mentioned on the label. This transparency ensures that consumers and regulatory authorities can easily identify the product and the specific alterations made.

## Example of Labelling Requirements

To illustrate the labelling requirements, the memorandum provides an example: if a drug is intended for CGHS (Central Government Health Scheme) supply, the additional information to be added on the label should read “CGHS Supply Overprint.” This example highlights the need for clear and accurate labelling to reflect the intended use of the drug.

## Conclusion

The recent Office Memorandum issued by the Directorate General of Health Services and the Central Drugs Standard Control Organization provides essential clarification on the comprehensive permission for imported drugs for labelling and overprinting under Rule 104A of the Drugs and Cosmetics Rules, 1945. By outlining the specific requirements for importers, facility and personnel standards, and compliance with current provisions, this document ensures that the labelling process is conducted in a manner that adheres to regulatory standards while enabling the import of necessary drugs.

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