# CENTRAL DRUGS STANDARD CONTROL ORGANISATION
# DIRECTORATE GENERAL OF HEALTH SERVICES,
# MINISTRY OF HEALTH AND FAMILY WELFARE
# GOVERNMENT OF INDIA

## Central Drugs Standard Control Organisation

## Guidance Document

**Title:** **Guidance document on common submission format for issuance of No Objection Certificate for export of unapproved/approved new drugs/Banned drugs.**

**Dated:**

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## A. INTRODUCTION

A manufacturer holding valid license copy in Form -25 and From- 28 can obtain No Objection Certificate from Zonal/Sub Zonal offices of Central Drugs Standard Control Organisation (CDSCO) for export purpose only for approved / unapproved new drug / banned drug in India.

## B. PURPOSE

Requirement for the common submission format for issuance of No Objection Certificate for export of unapproved/approved new drugs/Banned drugs from India. This document made as per guidelines issued by Ministry of Health and Family Welfare for Export purpose and Rule 94 of the Drugs and Cosmetic Act, 1940.

## C. SCOPE

This document is applicable for the manufacturer to obtain No Objection certificate Zonal/Sub Zonal offices of Central Drugs Standard Control Organisation (CDSCO) for export purpose.

## D. PROCEDURE

**Requirement for Common submission Format for issuance of No Objection Certificate for export of unapproved / approved new drugs / Banned drugs from India**

The Following documents are required to be submitted in the following manner and order for issue of the No Objection Certificate for export of drugs from India: -

1. **Covering Letter: -** The covering letter is an important part of the application and should clearly specify the intent of the application. The list of documents that are being submitted (Index with page no's) as well as any other important and relevant information may be provided in the covering letter. The covering letter mentioning list of products to be exported clearly indicating name of the drug, dosage form, composition and strength pack size along with quantity and country to be exported duly signed and stamped by the authorized signatory, indicating the name & designation of the authorized signatory along with the name and address of the firm. Each application should be made by the manufacturer only.

2. **Purchase Order: -**

    a. Order from the foreign buyer either in the name of manufacturer or in the name of trader mentioning list of products to be exported clearly indicating name of the drug, dosage form, composition and strength pack size duly signed by the competent authority with specific destination point of the importing country. In case of purchase order in the name of trader further a letter from the trader in the name of manufacturer is required to be submitted along with the application
    b. It should be signed by the competent authority/person with a valid purchase order no. and recent date not more than 6 month prior to the application made by the firm.

3. **Manufacturing License: -** License issued by the State Licensing Authority should be enclosed along with each application for the required location to manufacture the drug for export purpose.

4. **Performa Invoice: -**

    a. A copy of Performa invoice from the importing country should accompany with application for import of unapproved Active Pharmaceutical Ingredients, used in the drug formulation.
    b. A copy of Performa invoice duly signed by the competent authority should be addressed to the manufacturer mentioning the required quantity of the bulk drug.

## 5. Registration Certificate: -

a. For the export of drugs which are banned in India by Central government, which coming under list of drugs prohibited for manufacture and sale through gazette notifications under section 26a of drugs & cosmetics act 1940 by the ministry of health and family welfare.
b. A copy of registration certificate from the specific importing country along with composition and strength of the drug should accompany with the application
c. Registration certificate should be provided in the name of manufacturer.

## RULES RELATED TO EXPORT OF DRUGS FROM INDIA

### Rule 94: LABELLING AND PACKING OF DRUGS OTHER THAN HOMOEOPATHIC MEDICINES

(1) Labels on packages or containers of drugs for export shall be adapted to meet the specific requirements of the law of the country to which the drug is to be exported but the following particulars shall appear in a conspicuous position on the innermost container in which the drug is packed and every other covering in which that container is packed:

(a) name of the drug;
(b) the name, address of the manufacturer and the number of the licence under which the drug has been manufactured;
(c) batch or lot number;
(d) date of expiry, if any:

[Provided that where a drug, not classified under Schedule F, Schedule F(1) and Schedule X, blood products, Narcotic and Psychotropic Substances is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the Licensing Authority mentioned in Rule 21.]

[(2) The provisions of Rules 96 to 101 inclusive, shall not apply to a medicine made up ready for treatment, whether after or without dilution, which is supplied on the prescription of a registered practitioner provided that:

(*i*) The medicine is labelled with the following particulars: **–**
(*a*) The name and address of the supplier;
(*b*) The name of the patient and the quantity of the medicine;
(*c*) The number representing serial number of the entry in the prescription register;
(*d*) The dose, if the medicine is for internal use;

[(*e*) The words “FOR EXTERNEL USE ONLY” shall be printed on the label if the medicine is for external application].
(*ii*) Condition (3) of the conditions in Rule 65 is satisfied.]

**Rule 95.** Prohibition of sale or distribution unless labelled.—Subject to the other provisions of these Rules, no person shall sell or distribute any drug (including a patent or proprietary medicine) unless it is labelled in accordance with these Rules.

**Rue 96**. Manner of Labelling .— (1) Subject to the other provisions of these Rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely :—

(*i*) the name of the drug−

[(*A*) for this purpose, [5][the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any, which shall be shown immediately after or under the proper name and shall be]—

(*a*) for drugs included in the Schedule F or Schedule F (1), the name given therein;
(*b*) for drugs included in the Indian Pharmacopoeia or the official pharmacopoeias and official compendia of drug standards prescribed in Rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters 'I.P., or, as the case may be, by the recognized abbreviations of the respective official pharmacopoeias and official compendia of drug standards;
(*c*) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters 'N.F.I.';
(*d*) for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance;

# GUIDELINES FOR THE EXPORT OF DRUG ISSUED BY MINISTRY OF HEALTH AND FAMILY WELFARE

Subject: - Clarification about issuing NOCs for manufacture of new “”Unapproved” drug solely for export.

With reference to the above subject, the undersigned is directed to inform you that following consultation with the Ministry of Law and in consonance with their advice, you may resume the earlier practice of issuing NOC’s to applications received for the above purpose –

While processing such applications the following conditions shall be taken into consideration:

1. The application shall provide copy of valid export order and NOC will be issued on a case by case basis against each such order.
2. The applicant shall identify the premises where the drug will be manufactured for export.
3. The applicant should mention whether the batch to be exported has undergone Quality control testing or shall be tested at the destined site.
4. The applicant shall ensure that the drug(s) manufactured on the basis of “NOC” given as per (1) above its exported and that no part of it is diverted for domestic sale in India.
5. The applicant shall make available for inspection of the appropriate authorities, on completion of the export orders, information regarding each consignment despatched, remaining stock of drug and related raw materials and intermediates in hand.
6. The applicant shall ensure physical destruction of all unexported quantity of drugs. This should be included as a condition of manufacturing license issued to the applicant by the State licensing authority.
7. The applicant shall ensure that the drug for which NOC has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.

It is requested that immediate action may be taken to operationalise the process and a report on action taken in this regard to clear the pending applications may be sent to this office by 22.3.99. A monthly agreement may hereafter be sent of the NOCs issued by DCG(I) in an appropriate format.