REGISTRATION OF INDIAN DRUG PRODUCT IN OVERSEAS MARKET

INTRODUCTION

1. Indian Pharmaceutical Market: The Indian Pharmaceutical industry has acquired a noteworthy position in the global pharmacy sector and has been achieving significant growth in the recent years. India is among the top six global pharmaceutical producers in the world. Presently there are 10,500 manufacturing units and over 3,000 pharmacy companies in India, growing at an exceptional rate. India has about 1,400 WHO GMP approved manufacturing units. India has been accredited with approximately 1,105 CEPs (Certificate of Suitability) more than 950 TGA approvals and 584 sites approved by the USFDA.

STRUCTURE OF INDIAN PHARMACEUTICAL SECTOR

Indian pharmaceutical sector can be divided into two major segments namely, active pharmaceutical ingredients (API) or bulk drugs and formulations. The API can be branded or generic and these ingredients will be a part of formulations, which will be used to treat acute or chronic disease. The structure of Indian pharmaceutical industry is detail in the figure below

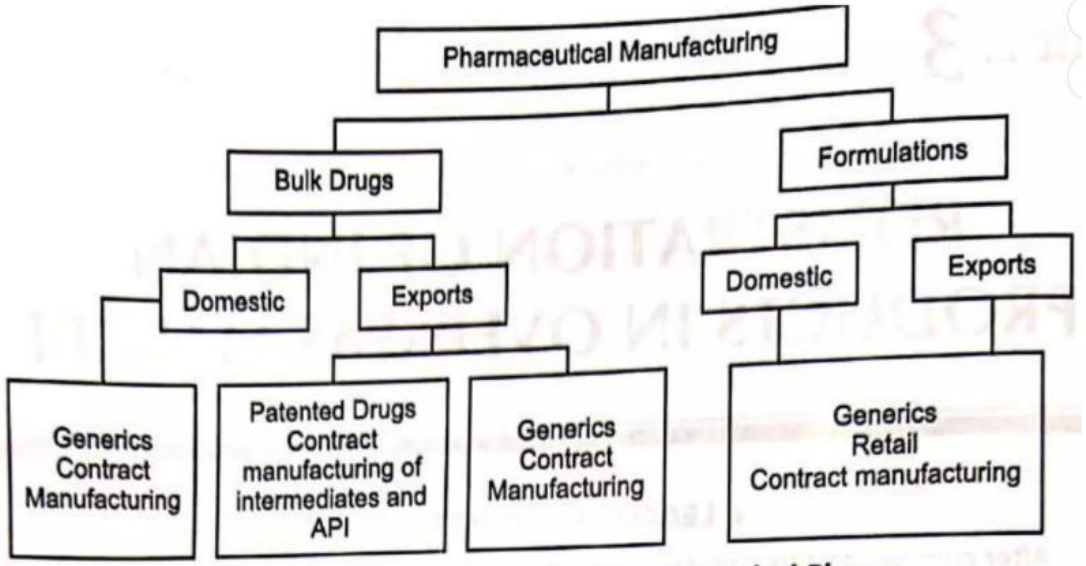

Fig. 3.1: Manufacturing by Indian Pharmaceutical Players

EXPORT OF PHARMACEUTICALS FROM INDIA

Administrative requirements of documents and procedure for export of drug from India. Explains export process of pharmaceutical products, government rules to export pharmaceutical products, export documentation to export pharmaceutical products:

A. **Introduction :** A manufacturer holding valid license copy in **form-25** and **form-28** can obtain No objection Certificate from zonal/sub zonal offices of Central Drugs Standard Control Organization (CDSCO) for export 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.

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:

- **Covering letter**: The covering letter mentioning list of products to be exported clearly indicating name of the drug, dosage form, composition and strength back size along with quantity and country to be exported Duly signed and stamp by the authorized signatory, indicating the name and designation of authorized signatory along with the name and address of the firm.
- **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.

(b) It should be signed by the competent authority/person with a valid purchase order number and recent date not more than 6 months prior to the application made by the firm.

- **Manufacturing license:** license issued by the state licensing authority should be enclose along with each application for the required location to manufacture the drug for export purpose.
- **Performa Invoice**: A copy of Performa invoice from importing country should accompany with application for import of API, used in drug formulation.
- **Registration Certificate:** A copy of registration certificate from specific importing country along with composition and strength of the drug should accompany with application.

RULES RELATED TO EXPORT OF DRUGS FROM INDIA

- **Rule 94:** labelling and packaging of drugs other than homeopathic medicines

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,

- **Name of the drug**
- **The name, address of the manufacturer and the number of the license under which the drug has been manufactured**
- **Batch or lot number**
- **Date of expiry**

The medicine is labelled with the following particulars:

- **The name and address of the supplier**
- **The name of the patient and the quantity of the medicine**
- **The number representing serial number of the entry in the prescription register**
- **The dose, if the medicine is for internal use**
- **The words -FOR EXTERNEL USE ONLY shall be printed on the label if the medicine is for external application.**

- **Rule 95:** Prohibition of sale or distribution unless labelled. Subject to the other provisions of these rules, no person shawl sale or distribute any drug unless it is labelled in accordance with these rules.
- **Rule 96:** Manner of labelling: subject to the other provisions of these rules, the 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 container is packed.

(i) The name of the drug

For this purpose, 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 F1

(b) For drugs included in the Indian Pharmacopoeia or the official pharmacopeia and official compendia of drug standards prescribed in Rule 124

(c) For drug 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 names, if any, published by The World Health Organization or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance.

RULES AND ACT RESPONSIBLE FOR IMPORT AND EXPORT OF PHARMACEUTICAL PRODUCTS

- Drugs and cosmetics act 1940 and rules 1945.
- The drugs (price control) order 1995.
- Medicinal and toilet preparation act 1956.
- Narcotic and psychotropic substances act 1985.
- Drugs and magic remedies act 1954

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

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

- The application shall provide copy of valid export order and NOC will be issued on a case by case basis against each such order.
- The applicant shall identify the premises where the drug will be manufactured for export.
- The applicant should mention whether the batch to be exported has undergone quality control testing or shall be tested at the destined site.
- The applicant shall ensure that the drug(s) manufactured on the basis of NOC given as above is exported and that no part of it is diverted for domestic sale in India.
- The applicant shall make available for inspection of the appropriate authorities, on completion of the export orders, information regarding each consignment dispatched, remaining stock of drug and related raw materials and intermediates in hand.
- 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.
- 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.

STEPS INVOLVED IN EXPORT OF PHARMACEUTICAL PRODUCTS

- Apply for IEC number.
- Get the customers mean contact the countries interested in importing the drug.
- Register the drug product in the country where you are going to export.
- Get the DCGI approval for exporting.
- Finalize the shipping method.
- Receive the purchase order from the country which is important and say invoice with complete product details.
- Sign the contract with the agency of the importing country.
- Pre shipment inspection.
- Export of the product.