



Received on 30 May, 2015; received in revised form, 24 July, 2015; accepted, 29 September, 2015; published 01 December, 2015

REGULATORY PROCESS FOR IMPORT AND EXPORT OF DRUGS IN INDIA

V. Senthil ^{*1}, R. Baviya Priyadharshini ¹, A. Ramachandran ¹ GNK Ganesh ¹ and Amber Shrivastava ²

Department of Pharmaceutical Regulatory Affairs ¹, Hospira healthcare Private Limited Visakhapatnam ², JSS College of Pharmacy, Ootacamund, Tamil Nadu, 643001, India.

Keywords:

Import, Export, NOC, RC, CDSCO, Performa Invoice

Correspondence to Author:

Dr. V Senthil

Professor,
Department of Pharmaceutical
Regulatory Affairs, JSS College of
Pharmacy, Ootacamund, (Constituent
College of JSS University, Mysore)
Tamil Nadu, 643001, India.


E-mail: senthil.v@jsscpooty.org

ABSTRACT: This article mainly focuses on the approval process of drug import and export from India. Now a day's foreign pharmaceutical companies have a better legal foundation for releasing new drugs in India. The Indian medical regulatory system has become more complicated, and new drugs can take a year or more to be approved for marketing. Ever-changing laws and regulations are driving demand for regulatory affairs professionals to provide the current needs of industries for the global competition and who can help pharmaceutical companies to effectively bring their medical products to the Indian market. In today's competitive scenario, the reduction of the time taken to launch the product is imperative and hence vital for company's success. This article will be helpful to all pharma manufacturer/importer, regulatory, preclinical, formulation scientists, and clinical trial professional who are involved directly or indirectly in new drug registration process. Need integrated knowledge and broad perspectives which you need to effectively manage the regulatory process for approval of new drugs in India.

INTRODUCTION: All around the globe, People are in need of medicines; some of the medicines are manufactured and available to them locally. For the remaining percentage the drug has to be imported from other countries. This emphasizes the trade of the drugs from one place of the world to another. Such a trade must be regulated in either way, both ethical and business oriented. Some of the organisations which regulate Pharma Business are World Trade Organisation (WTO), International Trade Organisation (ITO), and World Health Organisation (WHO).

Apart from this, every country has its own laws and legislations for the purpose ¹⁰.

India occupies a third largest position in the world in the field of Pharmaceutical industry. These industries are regulated by the Ministry of Health & Family Welfare and Ministry of Chemical & Fertilizers. Despite of its position in Pharmaceutical market and its growing economy, a well sophisticated Research and Development is not affordable due to various reasons. To overcome this pitfall, India opens up its pharmaceutical market to MNC's and it encourages the trading of the drug in and out of the country. Most of the drugs for the Indian market are imported from the European Union followed by North America and Asia. India has a special policy for the purpose of Import and Export called as "EXIM" policy. This policy gives way to quantitative as well as

QUICK RESPONSE CODE	DOI: 10.13040/IJPSR.0975-8232.6(12).4989-99
	Article can be accessed online on: www.ijpsr.com
DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.6(12).4989-99	

qualitative improvements in the field of Research and Development activities².

The Central Drugs Standard Control Organisation (CDSCO) regulates the import and export of the drugs in the country, through 11 Port offices located in different parts of the country. CDSCO regulates the manufacture, sale, import, export, and clinical research of drugs in India by the following rules and acts³.

1. Drugs and Cosmetics act, 1940 and Rules, 1945.
2. Pharmacy act, 1948.
3. Drugs and Magic Remedies act, 1954.
4. Medicinal and Toilet Preparation act, 1956.
5. Narcotic and Psychotropic Substances act, 1985.
6. The Drugs (Prices Control) order, 1995.

The CDSCO also work through state authorities. While, the central authorities are responsible for approval of new drugs, clinical trials in the country; laying down the standards for the drugs control over the quality of imported drugs coordination of the state drug control organisations; the state authorities regulates manufacture, sale and distribution of drugs, licensing drug testing laboratories, approving drug formulations for manufacture, carrying out pre and post licensing inspections, for the drugs manufactured and marketed in the respective states^{1, 2, 6}.

The new patent regime has ushered in the era of product patents for the pharmaceutical sector, in line with the obligations under the World Trade Organization (WTO) and Trade- Related Aspects of Intellectual Property Rights (TRIPS) Agreement. As a result, the Indian pharmaceutical industry has become self-reliant in several areas and has developed a sounder and technologically advanced R&D segment.

The industry offers several opportunities for investments and trade owing to the following advantageous features:

- 1) Self-reliance displayed by the production of 70% of bulk drugs and almost the entire requirement of formulations within the country;
- 2) Low cost of production and R & D of quality bulk drugs and formulations
- 3) Strong scientific, innovative and technical manpower
- 4) Increasing balance of trade in pharma sector.
- 5) Efficient and cost effective source for producing generic drugs, especially the drugs going off patent in the next five years.
- 6) Excellent center for clinical trials in view of the diversity in population.
- 7) Fast growing biotech industry which has great potential in the international market.

Apart from its strength in manufacturing and exporting allopathic medicines, the systems of medicines like Ayurveda, Unani, Siddha, Yoga, Naturopathy and Homeopathy are also prevalent in the country^{4, 11}.

Procedure for Import and Registration of Drugs:

Form and Manner of Application

A. Import License:

1. An application for an import License shall be made to the licensing authority in Form 8 for drugs excluding Schedule X, and in Form 8-A for Schedule X drugs; either by the Manufacturer or by the Manufacturer's agent in India who is having the wholesale license for sale or distribution of drugs and shall be accompanied by a License fee of one thousand rupees for a single drug and one hundred rupees for each additional drug and by an undertaking

in Form 9 duly signed by or on behalf of the manufacturer.

2. Any application for import licence in Form 8 or 8-A, which shall be accompanied by a copy of Registration Certificate issued in Form 41 under Rule 27-A; in the case of emergencies the issue of Import License by the central government in Form 10 or 10-A without issuance of Registration Certificate under Rule 27-A, for reasons to be recorded in writing.
3. A fee of two hundred and fifty rupees shall be paid for a duplicate copy of licence, if the original is defaced, damaged or lost.

B. Registration Certificate:

1. Application for issue of a Registration Certificate shall be made to the licensing authority in Form 40, either by the manufacturer or authorized agent in India under this rule and shall be specified in the sub rule (3) and the information and undertakings specified in Schedule D-1 and Schedule D-II duly signed by on behalf of the manufacturer.
2. The authorization by a manufacturer to his agent in India shall be documented by a power of attorney executed and authenticated either in India before a First Class Magistrate, or in the country of origin before such an equivalent authority, the certificate of which is attested by the Indian Embassy of the said country, and the original of the same shall be furnished along with the application for Registration Certificate.
3. (i). A fee of one thousand and five hundred US dollars shall be paid along with the application in Form 40 as registration fee for his premises meant for manufacturing of drugs intended for import and use in India.

(ii). A fee of one thousand US dollars shall be paid along with the application in Form 40 for the registration of a single drug meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional drug.

4. The fees shall be paid through a Chalan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110 001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104- Fees and Fines"; in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank.
5. The applicant shall be liable for the payment of a fee of five thousand US dollars for expenditure as may be required for inspection or visit of the manufacturing premises or drugs, by the licensing authority or by any other persons to whom powers have been delegated in this behalf by the licensing authority under rule 22.
6. The applicant shall be liable for the payment of testing fee directly to a testing laboratory approved by the Central Government in India or abroad, as may be required for examination, tests and analysis of drug.
7. A fee of three hundred US dollars shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.
8. No Registration Certificate shall be required under these rules in respect of an inactive bulk substance to be used for a drug formulation, with or without Pharmacopoeial conformity⁴.

Licenses for of drugs manufactured by a single Applicant:

A. Import:

A single application may be made, and a single License may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer. (Provided that the drugs or classes of drugs are manufactured at one factory or more than one factory functioning conjointly as a single manufacturing unit: Provided further that if a single manufacturer has two or more factories

situated in different places manufacturing the same or different drugs a separate License shall be required in respect of drugs manufactured by each such factory.).

B. Registration Certificate:

A single application may be made, and a single Registration Certificate in Form 41 may be issued in respect of the import of more than one drug or class of drugs, manufactured by the same manufacturer.

Specified before a license in form 10 or form 10-a is granted:

1. A License in Form 10 or in Form 10-A shall be granted by the licensing authority having regard to-
 - i) The premises, where the imported substances will be stocked.
 - ii) The occupation, trade or business ordinarily carried out by the applicant:
 - a. That the applicant has not complied with the provisions of the Act or these rules, or
 - b. That by reasons of- His conviction under Narcotic Drugs and Psychotropic Substances Act and Previous suspension or cancellation of the License granted to him.
2. Any person who is aggrieved by the order passed by the licensing authority ⁴.

Grant:

A. Import License:

1. On receipt of an application for an import License in the form and manner prescribed in Rule 24, the licensing authority shall on being satisfied, that, if granted, the conditions of the License will be observed, issue an import License in Form 10 or Form 10-A, as the case may be.
2. A License, unless, it is sooner suspended or cancelled, shall be valid for a period of three

years from date of its issue and for a fresh license is made three months before the expiry.

B. Registration Certificate:

1. On receipt of an application for Registration Certificate in the Form and manner specified in rule 24-A, the licensing authority shall, on being satisfied that, if granted, the conditions of the Registration Certificate will be observed, issue a Registration Certificate in Form-41.
2. If the applicant does not receive the Registration Certificate within the period as specified in provision to sub rule (1), he may appeal to the Central Government.
3. A Registration Certificate, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue and for a fresh Registration Certificate is made nine months before the expiry of the existing certificate.

Suspension and cancellation:

Both the Import License and Registration Certificate will be suspended or Cancelled, if the manufacturer or licensee fails to comply with any of the conditions, the licensing authority may after giving the manufacturer or licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel it for such period as it thinks fit either wholly or in respect of some of the substances to which it relates.

The drugs in the schedule C and C₁ are prohibited for import into the country after the expiry of potency of the drug product.

If the drug is banned in the country of origin then it is prohibited from importing into the country except for the purpose of Examination, test or Analysis ⁴.

Packaging and Labelling:

A. Imported Drugs: Drug shall be packed and labelled in conformity with the rules parts IX and X and also Schedule F (1), in the case of drugs for Veterinary use is Part XII.

B. Packing of Patent or Proprietary Medicine:

Patent or proprietary medicines shall be imported in bulk containers, applicant need to get permission from the licensing authority at least three months prior to the date of import and the validity will be twelve months from the date of issue.

New Drugs for the treatment of Patients: ¹²

A. Import:

- a. No new drug shall be imported for except under a License in Form 11- A, and the said drug has been approved for marketing in the country of origin.
- b. The Licensee shall use the substances or drugs imported under the License.
- c. The Licensee shall allow an Inspector authorized by the licensing authority with or without prior notice.
- d. The Licensee shall keep a record, and shall submit the report half yearly to the licensing authority.
- e. The Licensee shall comply with other requirements, made under Chapter III of the Act and of which the licensing authority has given to him not less than one month's notice.
- f. The drug shall be stored under proper storage condition and shall be dispensed under supervision of a registered Pharmacist.
- g. The quantity of single drug imported shall not exceed 100 average doses per patient.

B. Application for License:

- a. An application for an import License for small quantities of a new drug, as defined in rule 122-E for the purpose of treatment of patients.
- b. The licensing authority may require such further particulars to be supplied, as he may consider necessary.
- c. Every application in Form 12-AA shall be accompanied by a fee of one hundred rupees for

a single drug and an additional fee of fifty rupees for each additional drug.

- d. The fees shall be paid through a challan in the Bank of Baroda.

C. Cancellation of License:

- a. A License for import of small quantities of a new drug, defined in rule 122-E, for the purpose may be cancelled by the licensing authority for the conditions subject to which the License was issued.
- b. A licensee whose License has been cancelled may appeal to the Central Government within three months of the date of the order ⁴.

Import of New Homeopathic Medicine:

‘New Homoeopathic Medicine’ means:

1. A Homoeopathic medicine which is not specified in the Homoeopathic Pharmacopoeia of India or United States of America or of the United Kingdom or the German Homoeopathic Pharmacopoeia; or
2. Which is not recognized in authoritative Homoeopathic literature as efficacious under the conditions recommended; or
3. A combination of Homoeopathic medicines containing one or more medicines which are not specified in any of the Pharmacopoeias referred to in clause (i) as Homoeopathic medicines and also not recognized in authoritative Homoeopathic literature as efficacious under the conditions recommended.

New Homoeopathic medicine shall not allow to import except under the permission of the Licensing Authority, licensee shall submit the document which explains the therapeutic efficacy ⁶. No Homoeopathic medicine shall be imported unless it is packed and labelled in conformity with the rules in Part IX- A ^{1, 5, 7}.

Procedure for the Import of Drugs:

1. If the Customs Collector has reason to doubt any drugs comply with the provisions of

Chapter III of the Act and Rules, and if requested by an officer appointed for this purpose by the Central Government shall, take samples of any drugs in the consignment and forward them to the director of the laboratory appointed for this purpose.

2. If an importer who has given an undertaking under the proviso to sub-rule (1) is required by the Customs Collector to return the consignment or any portion thereof he shall return the consignment or portion thereof within ten days of receipt of the notice.
3. If the Director of the laboratory appointed for the purpose by the Central Government or other officer empowered by him, subject to the approval of the Central Government, reports to the Customs Collector that the samples of any drug in a consignment are not of standard quality, or the drugs under provisions of Chapter III of the Act or the Rules and that the contravention is such that it cannot be remedied by the importer, the Customs Collector shall communicate the importer who shall, within two months of his receiving the communication either export all the drugs or destroyed.

The importer may within fifteen days of receipt of the report make a representation against the Customs Collector, and the Customs Collector shall forward the representation with a further sample to the licensing authority, the report of the Director of the Central Drugs Laboratory, shall pass orders thereon which shall be final.

4. If the Director of the laboratory appointed for the by the Central Government or any officer empowered by him, subject to the approval of the Central Government reports to the Customs Collector that the samples of any drug contravene in any respect the provisions of Chapter III of the Act or the Rules and that the contravention is remedied by the importer, the Customs Collector shall communicate the report forthwith to the importer and permit him to import the drug and writing not to dispose of the drug without the permission of the officer authorized in this purpose.

The drugs specified in Schedule D shall be exempt from the provisions of Chapter III of the Act and of the Rules made there under, and subject to conditions specified in that Schedule.

5. Drugs, consignments of which are in transit through India to foreign countries and which shall not be sold or distributed in India shall be exempted from the requirements of Chapter III of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made there under. The importers shall produce documents at the time of import in India to get import license⁴.

Common Submission Format for Import and Registration of Bulk Drugs and Finished Formulations of Bulk Drugs and Finished Formulations in India:

Requirements for Registration of Drugs in Form 40:

1. Covering Letter:

This contains the list of documents shall be submitted and any other information provided, it shall be duly signed and stamped by the authorized signatory along with the name and address of the firm.

2. An Authorization Letter:

An Authorization letter in original issued by Director/Company Secretary/Partner of the Indian agent firm revealing the name & designation of the person authorized to sign Form 40, Power of Attorney, etc., it shall be submitted at the time of registration along with duly self-attested photocopies.

3. Form 40 & TR 6 Challan:

It shall be filled as per Drugs & Cosmetics Rules, signed and stamped along with name & designation and date of the Local Authorized Agent. Performa shall be enclosed at Annexure-I. Payment shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, New Delhi, through the electronic code of the bank.

4. Power of Attorney:

The authorization by a manufacturer to his agent in India shall be documented by Power of attorney authenticated in India or by country of

origin, the certificate shall be attested by Indian Embassy of the said country and original copy shall be submitted along with the application for Registration Certificate (RC). Performa for Power of Attorney (POA) is enclosed at Annexure III. The authorized agent will be responsible for manufacturer's business activity, in India. While submitting the Power of Attorney, the following shall be needed:

It shall be signed and stamped by the manufacturer as well as the Indian Agent indicating the name & designation of the authorized signatories.

It shall be clearly lists the names of all the proposed drugs if possible along with their uses. Further, the names of the proposed drug should correlate with Form 40, Free Sale Certificate or Certificate of pharmaceutical product (COPP) as per WHO-GMP certification scheme.

The names & addresses of the manufacture and the Indian Agent stated in the Power of Attorney should correlate with the Form 40. Multiple sites are in tabular form. And the Fresh POA shall be submitted at the time of Re-Validation of RC.

5. Wholesale License

A duly attested and valid copy of Wholesale License for sale or distribution of drugs under Drugs and Cosmetics Rules in Form 20B & 21B or its renewal in Form 21C issued to the manufacturer or its agent by the State Licensing Authority in India.

6. Undertaking: Signed & stamped by the manufacturer/Authorized agent indicating the name and designation of the authorized signatory required to be submitted as per Performa for Schedule D (I) is enclosed at Annexure IV along with CTD module 1 covering the Schedule D (I) requirement.

The requirements for Plant Master File are enclosed at Annexure V.

7. Modules 2-5 Covering the schedule D (II) requirements:

Standard of the Drug: Second Schedule of the act explains Imported drugs shall be compile

with the standard which are there in IP, USP, BP, EP, etc.,

Label Submission: True copy of the Label as per Rule 96, if it is in IP means as per label claim in IP.

Testing of Drugs:

For Registration of Bulk Drugs, the consecutive three batches shall be submitted to the laboratory for the analysis and reanalysis along with specifications, Method of analyses, COA tested in their laboratory, impurity Standards, marker compounds, Reference Standard along with its COA where ever applicable.

8. Free Sale Certificate (FSC): Free Sale Certificate should state that the proposed drug is freely sold in Country of Origin and can be legally exported.

9. Certificate of Pharmaceutical Products (COPP): The valid copy of GMP Certificate or COPP as per WHO scheme for each drug issued by the National Drug Regulatory Authority of the country of origin. Format for COPP is enclosed at Annexure VII.

10. Manufacturing License: The valid copy of the Manufacturing License or Market Authorization certificate issued by the National Drug Regulatory Authority of the Country of origin. If available, free sale certificate also be submitted.

11. Product Registration Certificate: The valid copy of Product Registration Certificate wherever applicable in respect of the foreign manufacturing sites.

a. Soft copy of the Plant Master File and Drugs Master File shall be submitted along with the application.

b. All certificates submitted shall be within the valid period. All the regulatory and legal documents in separate file and Plant Master File and Drug Master File as separate files.

c. In case, the item considered as drug as per the definition of section 3 (b) of the Act in

India but not registered as drug in the country of origin a legal undertaking from the manufacturer and approval from the competent authority of the country of origin duly notarized and apostle should be submitted.

- d. The application of r-DNA products should be made separately as per the guidance document for submissions of biological.
- e. In case of bulk drug, if the same is approved in EU/USA etc. DMF approval

number may mention on the covering letter itself.

- f. In case of toll manufacturer to be registered for a drug, the POA shall be signed by the legal manufacturer in the country of origin, this submitted as proof.
- g. POA should be supplemented with declarations in respect of sites involved in the manufacturing and testing of the applied drugs as per the format given hereunder:⁴

FOR BULK DRUGS (API):

Name of site where intermediates are manufactured	Name of site where API is manufactured	Name of site where API is Tested	Name of site where API is Packed	Name of dispatch site of API
---------------------------------------------------	----------------------------------------	----------------------------------	----------------------------------	------------------------------

FOR FINISHED FORMULATIONS (FF):

Name of API Source	Name of site where formulation is made	Name of site of Primary Packing	Name of site of Secondary Packing	Name of site of Testing & Release	Name of dispatch site of FF
--------------------	----------------------------------------	---------------------------------	-----------------------------------	-----------------------------------	-----------------------------

Renewal of Registration or Re-registration:

The application is to be made 9 months before the expiry of the Registration Certificate along with regulatory documentary compliance like Form 40, POA, GMP / COPP, Registration certificate, DMF, License etc.,

- i. Undertakings by the manufacturer or his authorized agent in India in respect of any administrative action taken due to adverse reaction, market withdrawal, regulatory restrictions, or cancellation of authorization, not of standard quality report of any drug pertaining to this Registration Certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the drug is marketed/sold or distributed.
- ii. Any change in manufacturing process, or packaging, or labelling or testing, or in documentation of any of the drug pertaining to this Registration Certificate
- iii. Any change in the constitution of the firm including name and /or address of the registered

office/ factory premises operating under this Registration Certificate.

- iv. Details of drugs imported in India during last three years.
- v. Submission of original RC issued⁴.

Requirements for Registration of Drugs in Form 10⁸:

- 1) Covering Letter
- 2) An Authorization Letter
- 3) Form 8-Duly signed and stamped by the Indian agent along with the name & designation of the authorized signatory, Performa is enclosed at Annexure-XII.
- 4) Form 9-Duly signed and stamped by the Indian agent along with the name & designation of the authorized signatory, if the form 9 is issued by the manufacturer, it shall be authenticated from Indian Embassy of the country of origin, Performa is enclosed at Annexure-XIV.

5) Requisite fee: Rs.1000 for 1 proposed drug and Rs.100 for each additional drug shall be paid at Bank of Baroda, New Delhi.

6) Wholesale license

7) Registration Certificate

Procedure for Obtaining No Objection Certificate (NOC) for Export of Unapproved/Approved New Drugs/Banned Drugs:

A Manufacturer holding valid license copy in Form-25 and Form-28 can obtain No Objection Certificate for export purpose only for approved / unapproved new drug / banned drug in India. The requirements are as per guidelines issued by Ministry of Health and Family Welfare for Export purpose and Rule 94 of the Drugs and Cosmetic Act, 1940⁹.

Rules Related to Export of Drugs from India:

A) Rule 94: Packing and labelling of drugs other than Homeopathic 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,

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

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:

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 EXTERNAL USE ONLY shall be printed on the label if the medicine is for external application.

B) Rule 96: Manner of Labelling:

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:

a. for drugs included in the Schedule F or Schedule F (1), the name given therein;

b. for drugs included in the 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 Organization or 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:

During the issue of NOC's for manufacture of new (Unapproved) drug solely for export, 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.

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 per the first condition and it 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 despatched, 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.

Requirement for Common Submission Format for Issue of NOC for Export: The following documents are required in the following manner and order for the issue No Objection Certificate (NOC) for export of drugs from India:

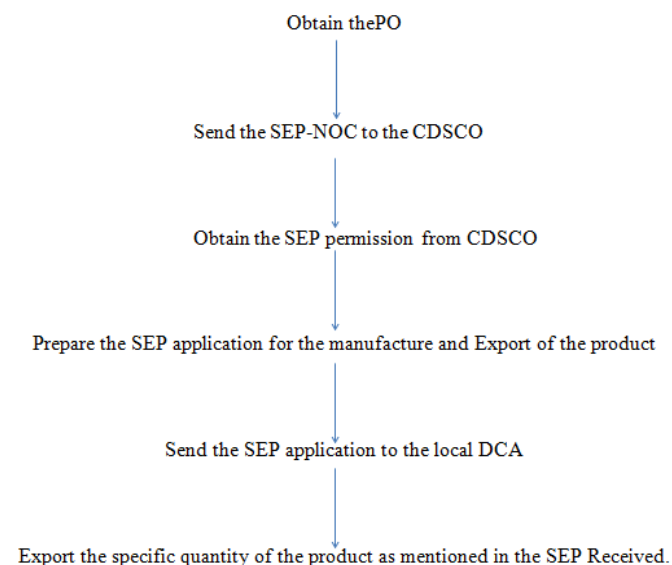
- I. Covering letter
- II. Purchase Order: Order from the foreign buyer either in the name of the manufacturer or trader with the list of products to be exported clearly indicating name of the drug, dosage form, composition and strength pack size duly signed by the competent authority with specific destination point of the importing country. It should be signed by the authority with a valid purchase order no. and recent date not more than 6 month prior to the application made by the firm.

III. Manufacturing License

IV. Performa Invoice: 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, it shall be duly signed by the competent authority.

V. Registration Certificate⁵

Process flow chart for issuance of no objection certificate for export:



CONCLUSION: The process of Import & Export of Drugs in any country including India is a lengthy process involving the various reviewing and registration processes; as a result lot of inputs are required to achieve the core objective of supply of medicine to the public.

The D & C rules (1945) prescribe various procedures for getting a drug approved to be imported/exported for human-veterinary use in the country. The rules are very clear prescribing the procedure to be adopted in this regard however; it is a tedious task to follow the procedures systematically and to meet the requirements. Latest amendments are given by the CDSCO according to the current Laws and Trading strategies for the approval for Import/Export in India. "Approval

Process for Import and Export of Drugs in India” gives an outlook on the entire process of getting a Drug Imported/Exported in India. The procedure and requirements vary considerably depending on the status of the Drug Applied.

The requirements for any drug to be approved for Import/Export as a New Drug for the first time are more stringent & informative than the requirements for an already approved Drug which are considerably relaxed.

ACKNOWLEDGEMENT: I express my gratitude to my Co authors of this articles who help me in writing this manuscript.

REFERENCES:

1. N. K. Dubey, Rajesh Kumar and Pramila Tripathi , Global promotion of herbal medicine: India’s opportunity - Current Science, 2004, 86(1)
2. World Health Organization (2012) Depression. http://www.who.int/mental_health/management/depression/en/
3. Economic Times (2014) Documentation. http://articles.economictimes.indiatimes.com/2014-05-06/news/49661672_1_toansa-usfda-indian-drug-makers
4. Hollister LE and Csernansky JG: Clinical Pharmacology of Psychotherapeutic Drugs. Churchill Livingstone, New York, Third Edition 1990.
5. Vijay Malik, Law Relating Drugs & Cosmetics Act 1940 and rules 1945 24th Edition, 2014.
6. Central Drugs Standard Control Organization (2014) Import & Registration Division <http://www.cdscsco.nic.in/forms/ShowSearchResult.aspx?Search=import>
7. Drugs and Cosmetic Act (2012) Import of New drug <http://www.cdscsco.nic.in/forms/ShowSearchResult.aspx?Search=clinical%20trials>
8. Sumit Kumar, Rishabh Panwar and Upendra Singh, Regulatory Affairs in the Pharmacy Curriculum, International Journal of Research and Development in Pharmacy and Life Sciences, 2013, 2(6): 690-698
9. Uma Vasireddy, G. Krishna Mohan, M. Lakshmi Narasu and P. V. Appaji, Impact of India’s formulation and bulk drug registrations with U.S. FDA on it exports: A stochastic analysis - Scholars Research Library, Der Pharmacia Lettre, 2011,3 (4):84-100
10. Ravi Kiran and Sunita Mishra, Research and Development, Exports and Patenting in the Indian Pharmaceutical Industry: a Post TRIPS Analysis, Eurasian Journal of Business and Economics 2011, 4 (7): 53-67.
11. Shamnad Basheer and Mrinalini Kochupillai, ‘Exhausting’ Patent Rights in India: Parallel Imports and TRIPS Compliance, Journal of Intellectual Property Rights, 2008, 13, September 2008:486-497. 22.
12. Pulok K. Mukherjee and Atul Wahile - Integrated approaches towards drug development from Ayurveda and other Indian system of medicines – Journal of Ethnopharmacology, 2006, 103(1): 25-35.
13. Pulok K. Mukherjee and Atul Wahile - Integrated approaches towards drug development from Ayurveda and other Indian system of medicines – Journal of Ethnopharmacology, 2006, 103 (1): 25-35.

How to cite this article:

Senthil V, Priyadarshini RB, Ramachandran A, Ganesh GNK and Shrivastava A: Regulatory Process for Import and Export of Drugs in India. Int J Pharm Sci Res 2015; 6(12): 4989-99. doi: 10.13040/IJPSR.0975-8232.6(12).4989-99.

All © 2013 are reserved by International Journal of Pharmaceutical Sciences and Research. This Journal licensed under a Creative Commons Attribution-NonCommercial-ShareAlike 3.0 Unported License.

This article can be downloaded to **ANDROID OS** based mobile. Scan QR Code using Code/Bar Scanner from your mobile. (Scanners are available on Google Playstore)