



## **IMPORTS & EXPORTS OF THERAPEUTIC GOODS**

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**Drug Regulatory Authority of Pakistan  
Islamabad - Pakistan**

## 1. HISTORY

This is the first edition of these guidelines.

## 2. APPLICATION – (Guidelines for Industry)

This document applies to the manufacturers, importers and individuals or organizations that intends to import or exports of human and veterinary therapeutic goods. These guidelines are intended to aid following :-

- i. Importers and manufacturer of therapeutic goods;
- ii. Health care professionals or investigators of clinical trials;
- iii. Hospitals/Government institutions/ non-Government organizations/trust etc.

## 3. PURPOSE

This guidance document is aimed at provision of an overview of the requirements, procedures and best practices for imports and exports in compliance with the legal and regulatory requirements for all therapeutic goods including finished pharmaceutical and biological drug products, active pharmaceutical ingredients (APIs) and drug substances (DS), Medical Devices, and Health & OTC Product (e.g. nutraceuticals, herbals, ayurvedic and homeopathic products, biochemic and Chinese products) and their raw materials.

This document is intended to provide an outline of the requirements for importing and exporting therapeutic goods for commercial purposes, as well as for bringing therapeutic goods for hospital/intuitional use or personal uses. These guidelines are meant to:-

- ✓ Outline the requirements and documentation for import and export of therapeutic goods
- ✓ Determine the eligibility; who can import or export therapeutic goods
- ✓ Elaborate procedure adopted by DRAP for verification and port clearance
- ✓ Describe the responsibilities of the entities involved in import and export

However, this document only emphasis on the requirements under the drug regulatory framework implemented by DRAP. Nevertheless, therapeutic goods are also subjected to additional statutory requirements enforced by other acts/regulations/conventions, such as the Custom Act, 1969, and control of Narcotics Act, 1997 etc., which are also required to be followed.



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#### **4. INTRODUCTION**

Drug Regulatory Authority of Pakistan (DRAP) is responsible for ensuring that therapeutic goods approved and available in market for the people of Pakistan must meet the prescribed standards of quality, safety and efficacy. DRAP has a regulatory oversight on imports of all type of therapeutic goods to determine whether they are permissible in accordance with the applicable drug laws and may refuse their entry in case of noncompliance to the regulatory requirements. These regulatory controlled are applied to prevent the infiltration of substandard and suspected falsified medicine into the supply system and to assure the access to standard quality therapeutic goods.

Infiltration of substandard and suspected falsified therapeutic goods poses serious threats for public health. In order to cope this challenge, DRAP in collaboration with the Custom Authorities, Drug Control Organizations (DCO) and Health Departments of Provincial Governments, has deployed administrative and regulatory controls to safeguard public health, aimed at ensuring that therapeutic goods are in conformity with all particulars with the relevant registration / enlistment holder (marketing authorization) and remain secure within the licensed distributors and retail outlets throughout the supply chain.

The main objective of these guidelines is to provide an overview of legal and regulatory requirements to importers and exporters of therapeutic goods, enabling them to comply with the applicable drug laws on import and export of therapeutic goods.

#### **5. LEGAL BACKGROUND:**

In addition to Pakistan Custom (Federal Board of Revenue), DRAP regulates the import and exports of therapeutic goods in collaboration with other responsible organizations. The Drug Regulatory Authority of Pakistan is mainly responsible to implement the relevant drug laws applicable for regulation of import and exports of therapeutic goods. The legal framework is established under the enabling provisions of following legal statutes (including but not limited to):-

- i). The DRAP Act, 2012
- ii). The Drugs Act, 1976
- iii). The Drugs (Import & Export) Rules, 1976



- iv). The Medical Devices Rules, 2017
- v). The Alternative Medicines & Health Products (Enlistment) Rules, 2014

Similarly, the information related to the legal and regulatory requirement of custom authorities are available on their [website](#).

## GLOSSARY

### Acronyms

<b>API</b>	Active Pharmaceutical Ingredients
<b>BE&amp;R</b>	Biological Evaluation & Research Division
<b>cGMP</b>	Current Good Manufacturing Practice
<b>CoPP</b>	Certificate of Pharmaceutical Product
<b>CTD</b>	Common Technical Document.
<b>DRAP</b>	Drug Regulatory Authority of Pakistan
<b>DML</b>	Drug Manufacturing License
<b>DS</b>	Drug Substance
<b>EEC</b>	Enlistment Evaluation Committee
<b>FDP</b>	Finished Drug Product
<b>FSC</b>	Free Sale Certificate
<b>H&amp;OTC</b>	Health & OTC Division
<b>ICH</b>	International Commission for Harmonization
<b>MDB</b>	Medical Devices Board
<b>MDMC</b>	Medical Devices & Medicated Cosmetics Division
<b>PE&amp;R</b>	Pharmaceutical Evaluation & Registration Division
<b>PIC/s</b>	Pharmaceutical Inspection Cooperation Scheme.
<b>RB</b>	Registration Board
<b>RRA</b>	Reference Regulatory Authority
<b>WHO</b>	World Health Organization

### Definitions

To these guidelines following terms shall have interpretation as described as hereunder:-

<b>Alternative Medicine</b>	Any product used exclusively in Homeopathic, Unani, Ayurvedic, Biochemic, Chinese or other traditional system of treatment
<b>Biologicals</b>	A drug produced by biological systems and which require standardization by biological assays according to the relevant and updated recommendations of the World Health Organization published in Technical Report Series and Biological Standardization Report and includes-

- (a) blood products including Plasma, Albumin, Clotting Factors, Factors VIII, IX, Mixed Clotting Factors Tractions, Fibrinogens, Immunoglobulins;
- (b) immunological products including Antisera, Antitoxins, specific Immunoglobulins;
- (c) in vivo diagnostics including Tuberculin's, Lepronin, Histoplasmin, Coccidioidin, Allergens, Allergens Extracts, Antibodies conjugated with isotopes for imaging studies;
- (d) antigens, cytokines/antibodies/cells injected to elicit a biological response;
- (e) vaccines, including: (i) bacterial vaccines including live, killed whole cell, protein sub-unit, polysaccharide or glyco-conjugate, toxin derivatives, and rDNA biotechnology developed. (ii) viral vaccines including live, inactivated, sub-unit, rDNA, conjugated; (iii) polyvalent combinations of vaccines containing combination of vaccines defined in e(i) and d(ii).
- (f) toxins and venoms including snake venoms, scorpion venoms etc ;
- (g) immunostimulants of biological origin including BCG vaccine for immunotherapy;
- (h) biotechnology products which are primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques
- (i) human interferons, natural hormones, recombinant antibodies, monoclonal antibodies and derivatives gene therapy products;

## Drugs

Includes following :-

- (a) any substance or mixture of substances that is manufactured, sold, stored, offered for sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of diseases, an abnormal physical state, or the symptoms thereof in human beings or animals or the restoration, correction, or modification of organic functions in human beings or animals, including substance used or prepared for use in accordance with the Ayurvedic, Unani, Homoeopathic, Chinese or biochemic system of treatment except those substances and in accordance with such conditions as may be prescribed;
- (b) abortive and contraceptive substances, agents and devices, surgical ligatures, sutures, bandages, absorbent cotton, disinfectants, bacteriophages, adhesive plasters, gelatin capsules and antiseptic solution;
- (c) such substances intended to be used for the destruction or repulsion of such vermin, insects, rodents and other organism as cause, carry or transmit disease in human beings or animals or for disinfection in residential areas or in premises in which food is manufactured, prepared. or kept or stored;
- (d) such pesticides as may cause health hazard to the public;
- (e) any substance mentioned as monograph or as a preparation in the Pakistan Pharmacopoeia or the Pakistan National Formulary or the International Pharmacopoeia or the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National





Formulary of the United States, whether alone or in combination with any substance exclusively used in the Unani, Ayurvedic, Homoeopathic, Chinese or Biochemic \_system of treatment, and intended to be used for any of the purposes mentioned in subclauses (a), (b) and (c); and (f) any other substance which the Federal Government may by notification in the official Gazette, declare to be a drug for the purpose of this Act.

<b>Export</b>	The sending or transporting of a Therapeutic goods abroad.
<b>Falsified Medical Products</b>	Medical products that deliberately or fraudulently misrepresent their identity, composition or source. Any consideration related to intellectual property rights does not fall within this definition. Such deliberate or fraudulent misrepresentation refers to any substitution, adulteration or reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product
<b>Health and OTC Products</b>	include probiotics and disinfectant, nutritional products, food supplements, baby milk and foods, medicated cosmetics, medicated soaps and medicated shampoos;
<b>Importation</b>	The act of bringing or causing any goods to be brought into a Pakistan
<b>Importer</b>	An individual or company or similar legal entity importing or seeking to import a medical product. A “licensed” or “registered” importer is one who has been granted a licence for the purpose.
<b>Licensing Authority</b>	The person responsible for authorizing imports (e.g. the ministry or department of trade or of imports and exports). The Federal Government has delegated the powers of Chief Executive Officer, DRAP [Licensing Authority as per Rule 9 & 22 of the Drugs (Import & Export) Rules, 1976] to the Assistant Directors (I&E) of respective field offices within the local limits of their area of jurisdiction, which further prompts the processing of application for clearance of imported consignment.
<b>Marketing Authorization</b>	A legal document issued by the competent national regulatory authority that authorizes the marketing or free distribution of a medical product in the respective country after evaluation for safety, efficacy and quality. In terms of quality, it establishes, inter alia, the detailed composition and formulation of the medical product and the quality requirements for the product and its ingredients. It also includes details of packaging, labelling, storage conditions, shelf-life and approved conditions of use.
<b>Medical Devices</b>	include:- (a) instruments, medical equipment, implants, disposables and software, used mainly for the purpose of diagnosis, monitoring and treatment of disease~ or (b) any other item which the Federal Government may, by notification in . the official Gazette, declare as medical device;



<b>Medical Product</b>	A term that includes medicines, vaccines, diagnostics and medical devices
<b>National Regulatory Authority</b>	The national agency responsible for the marketing authorization of, and other regulatory activities concerning, medical products.
<b>Starting material</b>	Any substance of defined quality used in the production of a medical product, but excluding packaging materials.
<b>Substandard Product</b>	<p>An authorized product that fails to meet either its quality standards or its specifications, or both. <b>unregistered product.</b> A medical product that has not undergone</p> <p>evaluation and/or approval by the NRA for the market in which it is marketed/ distributed or used, subject to permitted conditions under national or regional regulation and legislation. This medical product may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin.</p>
<b>Therapeutic Goods</b>	includes drugs or alternative medicine or medical devices or biologicals or other related products as may be notified by the Authority.

## 6. REGULATORY FRAMEWORK

The Authority regulates the import and export of therapeutic goods under the enabling provisions of the DRAP Act, 2012 and Drugs Act, 1976 and rules framed thereunder. Therapeutic goods are also subjected to additional regulatory oversight under their respective laws. Following laws provide the regulatory oversight on the various types of therapeutic goods with respect to their types:-

Sr.	Types of Therapeutics Goods	Applicable Laws
i.	<b>Pharmaceutical and Biological drugs</b> e.g., Finished drug products and their starting materials including Active Pharmaceutical Ingredients (APIs) and drug substances (DS), etc.	The Drug (Import & Export), Rules, 1976
ii.	<b>Medical Devices</b>	The Medical Devices, Rules, 2017
iii.	<b>Health &amp; OTC Product</b> e.g., nutraceuticals, herbals, ayurvedic and homeopathic products, biochemic and Chinese products) and their raw materials.	The Alternative Medicines & Health Products (Enlistment) Rules, 2014

All transactions concerning the consignments of therapeutic goods should be reviewed and released by the authorized officers of the Drug Regulatory Authority of Pakistan, and unless otherwise specified, only eligible importers (or exporters) will be permitted to import (or export) authorized therapeutic goods into (or out of) the country.

**Import and export of any adulterated, substandard, misbranded, and Counterfeit drugs are punishable under Schedule II and III of the DRAP Act, 2012 and Drug Act 1976.**

In order to facilitate the stakeholders and effective administration of regulatory oversight on import and export of therapeutic goods, DRAP has established following field offices in the country each in provincial capitals' city as under:-

Offices of DRAP	Address
DRAP field office, Islamabad	Telecom Foundation Complex, Sector G-9/4, Islamabad
DRAP field Office, Lahore	6-Bird wood Road, Lahore
DRAP field Office, Karachi	Block-B, Sindh Muslim Cooperative Housing Society, Karachi

DRAP field office, Peshawar	Benevolent Fund Building, Saddar Road, Peshawar
DRAP field office, Quetta	92-F, Satellite Town, Block-5, Chandni Chowk, Quetta

Applications for import and export of therapeutic goods are submitted on the prescribed format in the respective provincial field office of DRAP by the applicant entity / firm. The application is reviewed in accordance with the applicable drug laws under the defined standard operating procedures. The consignment is allowed to be released if found compliant or may be refused if they appear to be or have been found to be adulterated; meaning the product is contaminated, is not safe, unauthorized or does not otherwise meet applicable standards, misbranded meaning the labels contain false or misleading information, or the product is not registered / enlisted. If required, the consignment may be forbidden from release, or the consumption / utilization / sale of the products may be restricted.

## 7. LICENSING AUTHORITY

Chief Executive Officer, DRAP is the Licensing Authority, appointed by the Federal Government under Rule 9 and 22 of the Drugs (Import & Export) Rules, 1976. Licensing Authority is empowered to issue licenses to import drugs. This authority is further delegated upon the Assistant Directors Import & Export (I&E), Division of Quality Assurance, DRAP from the respective field offices within the local limits of their area of jurisdiction, which further prompts the processing of application for clearance of imported consignment.

## 8. IMPLEMENTATION OF CONTROLS

DRAP and Custom authorities is responsible for the compliance, monitoring and enforcement of laws applicable on the import and export of therapeutic goods in order to verify that regulatory requirements are being met. Both organizations work in collaboration to assess the compliance of the relevant legal statutes to ensure that imported therapeutic goods are safe, effective and of high quality.

Pakistan Custom officers may detain any therapeutic goods on suspicion of noncompliance with by exercising using their powers as described under the *Customs Act*. No therapeutic goods shall be released from the customs unless a clearance certificate has been obtained by the applicant from the licensing authority or an officer authorized on his behalf.

The authorized officers of DRAP also conduct risk-based inspections of imported consignments and if the therapeutic goods found to be non-compliant during the inspection their entry will be refused, or the stock may be seized. To verify whether the product meets the requirements, DRAP will assess the product and make an admissibility determination. The assessment may include taking samples of the product for laboratory analysis to confirm the product's composition and that it is not adulterated with an unspecified ingredient. To avoid potential delays at the borders, DRAP recommends that all pertinent information about the product and persons authorized to import (or export) the product be included with the shipment at the time of import.

The authorized officers of DRAP hold the authority to seize and detain any therapeutic goods that is believed to be in contravention of the applicable laws and rules. DRAP also has the authority to order unlawful imported goods to be removed from Pakistan, or where removal is not possible, to order the goods to be destroyed.

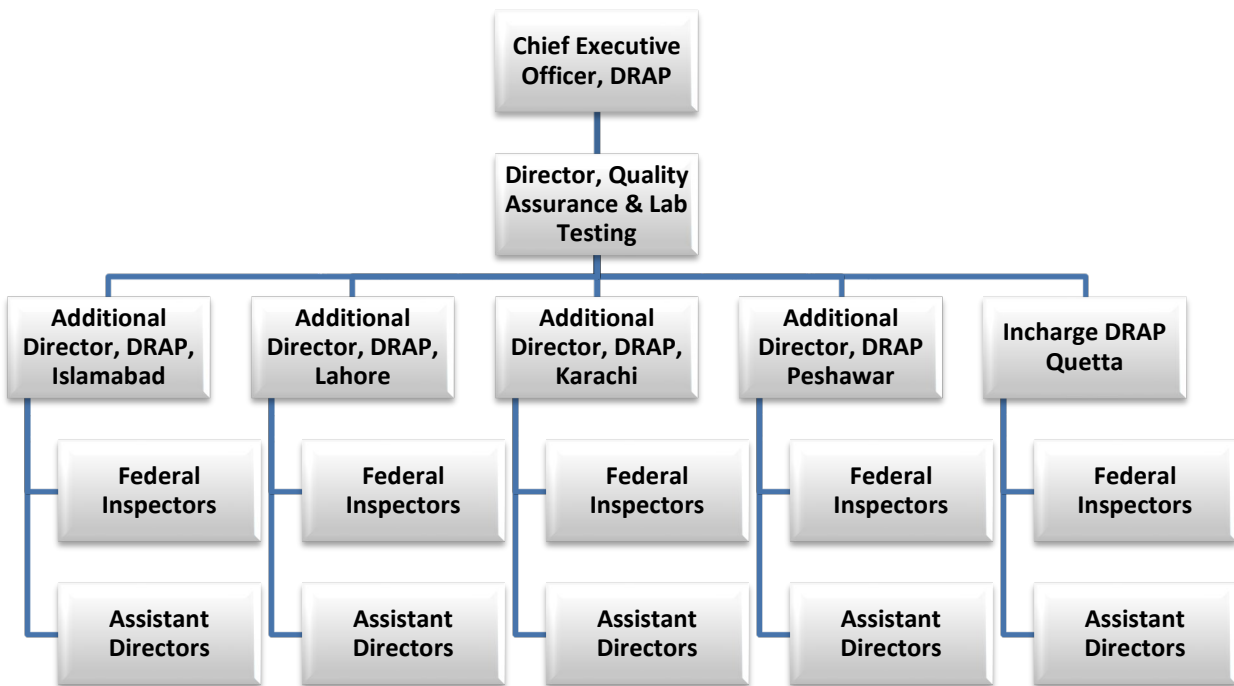


Figure 1: Regulatory Structure for Import and Export



## 9. ONLINE IMPORT / EXPORT APPLICATION SYSTEM

In line with the vision of Prime Minister of Pakistan, and to facilitate the therapeutic goods' industry for ease of business and provision of conducive environment for compliance to regulatory requirement, Drug Regulatory Authority of Pakistan (DRAP) has introduced an electronic application management system which will enable applicants and regulators to communicate electronically for management of import and export information of therapeutic goods.

Online Import / Export Application System is accessible through the [link](#) provided on the official [website](#) of DRAP. A [guidance document](#) on operational features of the online Import / Export Application System is also available to assist applicants for submission of information. This system enable applicants to maintain their all submissions related to import or export made to DRAP through an individualized dashboard for each user.

All the applications of therapeutic goods industry related to the import or export of therapeutic goods are to be submitted through [Online Import / Export Application System](#). However, following types are applications are processed separately as under: -

- Applications for obtaining NOC for import or export of drugs on personal use. Such applications are required to be submitted on separate portal named as "[Import/Export of Medical Products For Personal Use](#)"
- Applications for import of unregistered drugs and donations of therapeutic goods are required submitted in the physical formats to the office of the Additional Director, Import / Export, Division of Quality Assurance and Lab Testing, DRAP.

## 10. SUBMISSION OF REGULATORY FEE

DRAP has introduced an online fee challan system, available on the [link](#) provided at the official website of DRAP. This system help user in the selection of applicable regulatory fee for the required service(s) under the respective regulatory function. The applicant can generate the fee challan(s) for any required purpose.

## CHAPTER 1- IMPORTATION OF THERAPEUTIC GOODS

### 11.PHARMACEUTICALS AND BIOLOGICALS

Pharmaceutical and biological drugs can be imported by the followings:-

- Pharmaceutical and Biological drugs manufacturers
- Marketing Authorization / Registration Holders of finished pharmaceutical and biological drug products
- Clinical trials sponsor and principal investigator
- Non-Governmental organizations (NGOs) / Institutions as recipients of donations

Additionally, special permissions may be granted to following in public health interests or under special circumstances:-

- Persons authorized to import pharmaceutical / biological for personal use only
- Hospitals / Institutions authorized to import drugs for hospital use only.

The general criteria for importer eligibility, required documentations and import procedures for various types of therapeutic goods are as under:-

#### 11.1. Import of Pharmaceutical Raw Materials and Drug Substance of Biologicals :-

Raw materials including Active Pharmaceutical Ingredients, Drug Substances, excipients, and packaging material (other than finished goods) may be imported by the pharmaceutical firms having valid Drug Manufacturing License (DML) issued by the Division of Drug Licensing, DRAP for manufacturing of drug products registered to that firm by the Registration Board.

##### 11.1.1. Drug Import License:-

Manufacturers are required to obtain Drug Import License (D.I.L) for import of drugs other than finished drug (separate for import from each manufacturing site) by applying on Form 2 accompanied with the applicable fee and an undertaking on Form 3 duly signed on the behalf of manufacturer.

A D.I.L for import of other than finished drugs is issued on Form 5 and is valid for two years from the date of issuance, unless earlier suspended or cancelled.

### **11.1.2. Import of Controlled Substances: -**

In case of import of controlled substance, an import authorization from the Division of Controlled Drugs is also required.

### **11.1.3. Documentation requirements for import:-**

Authorized importers having valid drug import license shall apply to the relevant field office (Import & Export section) of DRAP to obtain a clearance certificate/signed invoice for release or clearance of the consignments of drugs from custom ports. Following documentation is required to be submitted:-

- Intimation of arrival of consignment of imported drug on Form -8
- Copy of Valid D.I.L (Form 5)
- Copy of License (DML) & Renewal
- Copy of Registration & renewal status under Section 23 of Drug Act
- Batch Certification (Form-7)
- Certificate of Analysis
- Monograph (latest testing reference) USP/BP/EU/JP etc., of raw material (if applicable / required)
- Valid API manufacturing license (for APIs) and GMP Certificate of the exporting firms by respective Drug Regulatory Authority
- Packing list
- Bill of landing (B.L) / Airway bill (A.W.B)
- Invoice (2 sets) with clearance certificate (02 sets)
- Percentage (%) remaining shelf life (as per IGM date)
- Name of warehouse Pharmacist
- Any exemption obtained from labelling and packaging rules
- Consumption details of previous consignment (if applicable / required).
- Duly signed stamped Consumption details of previous consignment along with undertaking of genuineness of consumption statement if the raw/ packaging material falls in any of the FBR/ Customs concessionary SRO.
- Deposited challan of applicable fee.

### **11.2. Import of Pharmaceutical and Biological Finished Drugs:**

Application for import of registered pharmaceutical and biological finished drug products can only be made by the importers who are marketing authorization / registration holders for that product(s), and has a drug sale license issued from the respective health department of provincial governments.



In case of import of controlled substance, an import authorization from the Division of Controlled Drugs is also required.

#### **11.2.1. Documentation requirements for import:-**

Importers are required to obtain a clearance certificate/signed invoice from the relevant field office (Import & Export section) of DRAP for clearance of consignments of drugs from custom ports, by submitting the followings:-

- Intimation regarding Import on Form -1
- Intimation of arrival of consignment of imported drug on Form -8
- Copy of Registration & renewal status under Section 23 of Drug Act
- Copy of Drug Sale License
- Batch certification on Form-7
- Certificate of Analysis
- Latest Testing Reference USP/BP/EU/JP etc of raw material (if required)
- Valid GMP Certificate of the exporting firms by respective Drug Regulatory Authority
- Packing list
- Bill of landing (B.L) / Airway bill (A.W.B)
- Invoice (2 sets) with clearance certificate (2 sets)
- Percentage (%) of remaining shelf life (as per IGM date)
- Name of warehouse Pharmacist
- Any exemption obtained from labelling and packaging rules
- Consumption details of previous consignment (if required).
- Duly signed stamped Consumption details of previous consignment along with undertaking of genuineness of consumption statement.
- Deposited challan of applicable fee.

#### **11.3. Import of Small Quantities of Drugs for Clinical Trial, Test and Analysis:**

Application for import of small quantities of drugs (IMP; investigational medical products) for clinical trials, testing and analysis can only be made by the sponsor / investigators of approved clinical trials sites or by the drug manufacturers having Drug Manufacturing License (DML) under Drugs (Import &Export) Rules, 1976 after obtaining license from Import & Export, Quality Assurance & Lab Testing Division, DRAP.

However, if such imports contain controlled substances, then an import authorization from the Division of Controlled Drugs will also be required.

### **11.3.1. Documentation requirements for import:-**

Documentation requirements for import of small quantities of drugs for clinical trial, test and analysis are as under:-

- Application for license to import small quantity of drugs on Form-4
- Deposited challan of applicable fee.
- Undertaking on Form-3
- Copy of License (DML) & its Renewal / In case of clinical trials copy of form V (License to act as Contract Research Organization or Clinical Trial Site or Laboratory) and Form VI (Approval to conduct the clinical trial, BA or BE study).
- Batch Certification on Form-7
- Certificate of Analysis
- Latest Testing Reference USP/BP/EU/JP etc of raw material
- Valid API manufacturing license (for APIs) and GMP Certificate of the exporting firms by respective Drug Regulatory Authority
- API requirement data, Complete testing protocols/Stability studies protocols.
- Any other document (s) Particularly Required
- Name of warehouse Pharmacist

### **11.4. Import of Un-registered/Unavailable Drugs by Hospitals/Institutions:-**

Application for import of un-registered/unavailable drugs can be made by the Hospitals/institutions after having a prior approval (NOC) from the DRAP, field offices. When consignment arrived at the port Hospital / institution shall obtain clearance from the DRAP field offices.

An application for obtaining NOC for import of un-registered/not available drugs by Hospitals/institutions shall accompanied following:-

- Formal application for obtaining NOC for import.
- Free Sale Certificate or Certificate of Pharmaceutical Product (CoPP) or any other document which authorized officer shall deem to fulfill the purpose.
- Certificate of analysis or conformance.
- Registration of Hospital/Institution
- An affidavit of stamp paper containing following conditions: -
  - i. The import will be made with the approval of Licensing Authority under the Rule-9 of the Drugs (Import & Export) Rules 1976
  - ii. The drug will not be sold or distributed in the market;
  - iii. The drug is on free sale in country of origin.
  - iv. The drug will be used for therapeutic purpose in the hospital or institutions only and not for the purpose of clinical trial, examination, test or analysis.

- v. Clearance certificate will be obtained from AD (I & E) concerned at the time of arrival of shipment before custom clearance. Consumption or utilization record must be maintained by the importer under supervision of qualified person.
- vi. The drug will be used in patients benefits only
- vii. The drug is not registered and/or not available in Pakistan.
- viii. The Drugs will be provided to patients on 'No Profit No Loss' basis.

Applicant will also submit soft copy of data (summary sheet) and each page of the dossier shall be duly signed and stamped.

### **11.5. Import of Medicines on Donation:-**

Application for import of donation medicines can be made by the Government Institutions, Non-Governmental Organizations (NGOs), International Non-Governmental Organizations (INGOs) or Hospitals after obtaining a No Objection Certificate (NOC) from the respective field office, DRAP, field offices.

Following documentations are required to be submitted for Import of medicines on donation:-

- Application for the NOC to import drugs on donation basis.
- Proof of free sale in country of export shall be accompanied with free sale certificate or Certificate of Pharmaceutical Product or any other document which authorized officer shall deem to fulfill the purpose.
- Certificate of analysis or conformance.
- Certificate of donation from donor.
- Copy of packing list.
- Copy of invoice
- Registration of NGO/ Hospital/Institution-
- An affidavit of stamp paper containing following conditions: -
  - i. The drug does not contain any narcotic or psychotropic ingredient;
  - ii. The drug is allowed to be sold freely in the country of its origin;
  - iii. The drug has minimum of six months expiry; and
  - iv. The drug shall not be sold, in any form in the market in Pakistan.

### **11.6. Import of Medicines for personal use:-**

Application for import of medicines for personal use can be made by the patient or by a family member for the import of unregistered / unavailable drugs, limited to the maximum supply of one hundred doses (100 doses). Application should accompany by a



prescription from a registered medical practitioner, (physician, dentist, etc.) also bearing PMC registration number of prescribers.

An application for import of drug for personal use shall be submitted to the relevant field office of DRAP in that province / state, or can also be submitted online via official website of DRAP or by using link: <https://public.dra.gov.pk/ie/noc> .

Following documents are required to be submitted Importation of medicines for personal use:-

- Copy of CNIC of patient and applicant (if applied by the family member)
- Valid prescription of authorized medical practitioner
- List of medicines / drug products to be imported along with name, manufacturer and quantities.

## **12. IMPORT OF MEDICAL DEVICES:**

Medical Devices can be imported after having registration of that Medical Devices from Medical Devices Division of DRAP. After that Importer has to obtain clearance certificate/signed invoice from the import and export section of DRAP. Medical devices are regulated by DRAP under the authority of the DRAP Act and the *Medical Devices Rules, 2017* . Medical devices are categorized into four classes (A,B,C &D) based on the level of risk related to their use. Medical devices without a medical device license/Registration may be imported through a request by a hospital under medical devices.

## **13.IMPORT OF ALTERNATIVE MEDICINES AND HEALTH PRODUCTS:**

Alternative Medicines & Health and OTC products are regulated under S.R.O.412(I)/2014(Alternative Medicines & Health and OTC products rules, 2014). For importation of finished product an importer has to obtain Form 6 (Provisional enlistment certificate as importer) and Form 7 (Provisional enlistment of product) from Health &OTC division of DRAP. For import of Raw material an importer has to obtain Form 6(Provisional enlistment certificate as Manufacturer) and Form 7 (Provisional enlistment of product). requirement for enlistment may be obtain from DRAP official website([dra.gov.pk](http://dra.gov.pk)) After fulfillment of enlistment a importer has to obtain clearance certificate for each consignment from import and export section of Quality Assurance and Lab testing division of DRAP.

## **CHAPTER 2- EXPORTATION OF THERAPEUTIC GOODS**

All types of therapeutic goods can be exported from Pakistan with the approval of DRAP. Exporters are required to get an NOC from the respective field office of DRAP on submission of an application with requisite documents.

### **14.EXPORT OF PHARMACEUTICAL AND BIOLOGICAL DRUGS**

Drug Manufacturers having drug manufacturing license can export their registered products from Pakistan. Similarly, Drug Sale license holders can also export products of their ally's manufacturer after having a license to export drug from the respective field office of DRAP. Following general conditions are required to met for export of therapeutic good:-

- Products are manufactured according to the GMP requirements
- Manufacturing site is a license facility .
- Therapeutic product is registered or enlisted as applicable.
- Export Order

#### **14.1. Drug Export License (D.E.L)**

An application for issuance of Drug Export License can be made on by a manufacturer having drug manufacturing license or a drug sale license holder. One export license is required in respect of export of more than one drug from same manufacture, however a separate license will be required in case of different manufacturing facility.

An application on Form 10 along with an undertaking on Form 11 duly signed by the respective drug manufacturer is required to be submitted for issuance of Drug Export License.

Drug Export License is issued on Form 9 , and will be valid for two years unless it is suspended or cancelled earlier.

#### **14.2. Export of Controlled Substances: -**

In case of export of controlled substance, an export authorization from the Division of Controlled Drugs is also required.



### **14.3. Documentation requirements for Export:-**

Authorized exporters having valid drug export license shall apply to the relevant field office (Import & Export section) of DRAP to obtain an NOC for export of drugs.

Following documentation is required to be submitted:-

- Drugs Sale License/ Drugs Manufacturing License with Renewal Status
- Copy of Valid D.E.L for other than Finished Drugs (Form 9)
- Copy of drug Registration & Renewal Status
- Form-7
- Certificate of Analysis
- Valid GMP Certificate of the exporting firm/ Last Panel Inspection Report
- Packing list
- Export Order
- Invoice (2 sets)
- remarks columns

### **15. EXPORT OF MEDICAL DEVICES**

Medical Devices having registration from Medical Devices Division of DRAP can be exported from Pakistan. Exporters are required to obtain an NOC from the respective field office of DRAP. Medical devices are regulated by DRAP under the authority of the DRAP Act and the Medical Devices Rules, 2017. Medical devices are categorized into four classes (A,B,C &D) based on the level of risk related to their use.

### **16. EXPORT OF ALTERNATIVE MEDICINES AND HEALTH PRODUCTS**

Alternative Medicines & Health and OTC products are regulated under S.R.O.412(I)/2014 (Alternative Medicines & Health and OTC products rules, 2014). Manufacturers of Health & OTC products can export their products.



## **17.STORAGE FACILITIES**

Many pharmaceutical products tend to degrade during on storage and some need to be stored under specified conditions such as 2–8 degrees °Celsius, cold storage. All Customs posts designated to handle consignments of pharmaceutical products should consequently be provided with secure storage facilities, with the required conditions including cold storage areas, where required. refrigerated compartments. If no pharmaceutical inspector or enforcement officer is employed on site, these facilities should be inspected periodically by the DRAP to ensure that all equipment is maintained and in good working order. The importing agency or agent should alert the customs authorities in advance of the anticipated arrival of consignments in order that they may be transferred from the international carrier to the designated storage facility with the minimum of out delay and, in appropriate cases, without breaking the cold chain.

Consignments of pharmaceutical products and pharmaceutical starting materials should be accorded high priority for clearance through DRAP and customs. Consignments of medical products and pharmaceutical starting materials, especially those requiring cold chain, are accorded high priority for clearance through customs, to avoid extended storage.



## **18.REFERENCES**

1. The DRAP Act 2012.
2. The Drug Act 1976.
3. The Drugs (Import & Export) Rules, 1976
4. The Medical Devices Rules, 2017
5. The Alternative Medicines and Health products Rules, 2014.
6. WHO guidelines on import procedures for medical products





**DRUG REGULATORY AUTHORITY OF PAKISTAN**

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