



IMPORTS AND 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, institutions and individuals, etc. that intend to import or export therapeutic goods for human and veterinary use.

3. PURPOSE

This guidance document is aimed to provide requirements, procedures and practices for imports and exports for any therapeutic good e.g. 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 applicable for import and export of therapeutic goods for commercial and non-commercial purposes. These guidelines are meant to:-

- ✓ Elaborate the requirements and documentation
- ✓ Determine the eligibility;
- ✓ Elaborate procedure adopted by DRAP for verification and port clearance
- ✓ Describe the responsibilities of the entities involved

However, this document only emphasizes on the requirements being adopted by the DRAP.



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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 import of all type of therapeutic goods to determine whether they are permissible in accordance with the applicable drug laws. DRAP may refuse entry of any therapeutic good in case of noncompliance to the regulatory requirements. These regulatory controls 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. In some cases, decisions are also taken to ensure the availability of unregistered / unavailable therapeutic goods to the persons in need.

Infiltration of substandard and suspected falsified therapeutic goods poses serious threats to the 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.

The main objective of these guidelines is to provide legal and regulatory requirements to importers and exporters of therapeutic goods, enabling them to comply with the applicable drug laws for import and export of therapeutic goods. These guidelines specify the format and content of the relevant applications and procedures to receive necessary authorizations or permissions by DRAP.

5. LEGAL BACKGROUND

In addition to Pakistan Custom (Federal Board of Revenue), DRAP also regulates the import and export of therapeutic goods in collaboration with other relevant organizations. The Drug Regulatory Authority of Pakistan is responsible to implement the applicable drug laws for regulation of import and exports of therapeutic goods. The legal framework is established under the enabling provisions of following legal statutes :-

- 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
- vi). Bio-Study Rules, 2017.
- vii). SRO for import of drugs as donation by any agency in Pakistan.
- viii). SRO for import of essential Life saving drugs by hospitals and institutions.



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



6. DEFINITION AND ACRONYMS

API	Active Pharmaceutical Ingredients
Authority	The Authority means Drug Regulatory Authority of Pakistan
BE&R	Biological Evaluation & Research Division
cGMP	Current Good Manufacturing Practice
CoPP	Certificate of Pharmaceutical Product
CTD	Common Technical Document
DML	Drug Manufacturing License
DRAP	Drug Regulatory Authority of Pakistan
DS	Drug Substance
EEC	Enlistment Evaluation Committee
FDP	Finished Drug Product
FSC	Free Sale Certificate
H&OTC	Health & OTC Division
ICH	International Commission for Harmonization
MDB	Medical Devices Board
MDMC	Medical Devices & Medicated Cosmetics Division
PE&R	Pharmaceutical Evaluation & Registration Division
PIC/s	Pharmaceutical Inspection Cooperation Scheme
RB	Registration Board
RRA	Reference Regulatory Authority
WHO	World Health Organization
Alternative Medicine	As defined in Section 2(ii) of the DRAP Act, 2012.
Biologicals	As defined in Schedule-I of the DRAP Act, 2012. ;
Drugs	As specified in Schedule-I of the DRAP Act, 2012..
Export	Sending or transporting of a Therapeutic goods abroad.
Health and OTC Products	As defined in Section 2(xv) of the DRAP Act, 2012. ;
Importation	Act of bringing or causing any goods to be brought into a Pakistan
Importer	An individual or company or legal entity importing or seeking to import a therapeutic good. A “licensed” or “registered” importer is one who has been granted a licence for this purpose.
Licensing Authority	Person responsible for authorizing imports and exports of therapeutic goods by the Federal Government.
Marketing Authorization	A legal document issued by the DRAP that authorizes the marketing or distribution of a therapeutic good in the country after evaluation for safety, efficacy and quality.
Medical Devices	As defined in Schedule-I of the DRAP Act, 2012;
Starting material	Any substance of defined quality used in the production of a medical product, but excluding packaging materials.



Unregistered un-enlisted product. Therapeutic Goods / A therapeutic good that has not been authorized by the DRAP for marketing/ distribution in the country.
As specified in Section 2(xxxvi) of the DRAP Act, 2012.

7. 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. Following laws provides the regulatory oversight on the various type of therapeutic goods

Sr.	Types of Therapeutics Goods	Applicable Laws
i.	Pharmaceutical and Biological drugs 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.	Medical Devices	The Medical Devices, Rules, 2017
iii.	Health & OTC Product e.g., nutraceuticals, herbals, ayurvedic and homeopathic products, biochemic and Chinese products) and their raw materials.	The Alternative Medicines & Health Products (Enlistment) Rules, 2014 The Drug (Import & Export), Rules, 1976
	Clinical trials	Bio-Study Rules, 2017

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 therapeutic goods prohibited under Rule 23 of the Drugs Act 1976 and Schedule II of the DRAP Act 2012 are punishable under Rule 27 of the Drugs Act 1976 and Schedule III of the DRAP Act, 2012 . However, unregistered / un-enlisted pharmaceuticals / alternative medicines can be imported by hospitals / institutions under special SRO after obtaining pre-approvals from DRAP. Unregistered / un-enlisted medical devices can also be imported by hospitals / institutions under relevant provisions of Medical Devices Rules, 2017 after obtaining NOC from DRAP. Whereas unregistered / un-enlisted therapeutic goods as donation can be imported under special SRO after obtaining NOC from DRAP.

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 provincial capitals' 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 online by the applicants on the following links:.

- i. For commercial purposes: ie.dra.gov.pk.
- ii. For personal use: <https://public.dra.gov.pk/ie/noc>.

The application is reviewed in accordance with the applicable laws under the defined standard operating procedures. The consignment is allowed to be released only if found compliant.

8. 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 / export drugs. This authority is further delegated to the Assistant Directors Import & Export (I&E), Division of Quality Assurance, DRAP from the field offices within the local limits of their area of jurisdiction.

9. IMPLEMENTATION OF CONTROLS

DRAP and Custom authorities are 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 acceptable quality.

Pakistan Custom officers may detain any therapeutic goods on suspicion of noncompliance by exercising 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 are found to be non-compliant during the inspection, clearance certificate will be refused, or the stock may be ordered not to dispose off or 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 of Therapeutic Goods



10. ONLINE IMPORT / EXPORT APPLICATION SYSTEM

In order 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 electronic application management system, namely online import and export system (OIES) which will enable applicants and regulators to communicate electronically for management of import and export related information and processing of applications related to therapeutic goods.

A guidance document (<https://www.dra.gov.pk/publications/guidelines/qa-It/>) on operational features of the online Import / Export Application System (for commercial purposes) is also available to assist applicants for submission of requisite information. This system enables users to maintain all their submissions through an individualized dashboard for each user.

All the applications of therapeutic goods industry related to the import or export of therapeutic goods are submitted through Online Import / Export Application System. However, following types of applications are processed separately : -

- Applications for obtaining NOC for import or export of drugs for personal use. Such applications are required to be submitted on separate portal "<https://public.dra.gov.pk/ie/noc>."
- Applications for import of unregistered drugs and donations of therapeutic goods for institutional/hospital patients' use are submitted in the physical form to the Additional Director of the respective field office of DRAP.

11. SUBMISSION OF REGULATORY FEE

DRAP has introduced an online fee challan system, accessible on the [link](#). 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 various required purposes.



CHAPTER 1- IMPORTATION OF THERAPEUTIC GOODS

12.IMPORT OF PHARMACEUTICALS AND BIOLOGICALS

Pharmaceutical and biological drugs can be imported by following:-

- Pharmaceutical and Biological drugs manufacturers
- Marketing Authorization / Registration Holders of finished pharmaceutical and biological drug products
- Clinical trials sponsor and principal investigator

Additionally, following special permissions in public health interests or under special circumstances:-

- For personal use.
- For hospital / institutional use. .
- Donations by Non-Governmental organizations (NGOs) / Institutions.

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

12.1.Import of Raw Materials for Drugs and Biologicals

Raw materials including Active Pharmaceutical Ingredients, drug substances excipients, and packaging material (other than finished goods) can be imported by the pharmaceutical firms having valid Drug Manufacturing License (DML) issued by the Division of Drug Licensing for manufacturing of drug / biological products registered in the name of that firm by the Registration Board. Drug Manufacturing License holders can also apply for import of Active Pharmaceutical Ingredients and Drugs Substances for Research and Development of un-registered drug/biological product.

12.1.1. *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 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.



Forms can be downloaded from this link <https://www.dra.gov.pk/publications/application-forms/#IandE>.

12.2.Import of Controlled Substances

In case of import of controlled substance (Narcotic Drugs, Psychotropic Substances and Precursor Chemicals), an import authorization from the Division of Controlled Drugs is also required in addition to Marketing Authorization by the Registration Board.

12.2.1 Documentation requirements for import

Applicants having valid drug import license shall apply through online portal (ie.dra.gov.pk.) to the relevant field office (Import & Export section) of DRAP to obtain a clearance certificate for release or clearance of their consignments of drugs/biologicals from custom ports. Following documents are required to be submitted electronically:-

- Intimation of arrival of consignment of imported drug on [Form -8](#)
- Copy of Valid D.I.L ([Form 5](#))
- Copy of License (DML) & Renewal (if applicable)
- Copy of Registration (Marketing Authorization) & renewal (if applicable)
- 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 principal manufacturer by relevant National Regulatory Authority
- Packing list
- Bill of landing (B.L) / Airway bill (A.W.B)
- Invoice Percentage (%) remaining shelf life (as per IGM date)
- 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.
- DRAP approved process flow chart for the manufacturing of API (by basic/ semi-basic manufacturers)
- Undertaking on stamp paper specifying the following:
 - The DML and drug registration are valid



- The genuineness of the documents provided therein is the responsibility of the applicant.

12.3.Import of Pharmaceutical and Biological Finished Drugs

Application for import of registered finished pharmaceutical and biological drug products can be made by the importers having valid marketing authorization / registration for that product(s), and has a drug sale license issued from the respective Provincial Health Department.

In case of import of controlled substance (Narcotic Drugs, Psychotropic Substances and Precursor Chemicals), additionally an import authorization from the Division of Controlled Drugs is also required.

12.3.1. Documentation requirements for import

Applicants shall apply through online portal (ie.dra.gov.pk.) to the relevant field office (Import & Export section) of DRAP to obtain a clearance certificate/ for clearance of consignments of finished drugs / biologicals from custom ports. Following documents are required to be submitted electronically:-

- Intimation regarding Import on [Form -1](#)
- Intimation of arrival of consignment of imported drug on [Form -8](#)
- Copy of Registration & renewal status (if applicable)
- 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)
- Packing list
- Bill of landing (B.L) / Airway bill (A.W.B)
- Invoice
- Percentage (%) of remaining shelf life (as per IGM date)
- Any exemption obtained from labelling and packaging rules
- Deposited challan of applicable fee.
- Undertaking on stamp paper specifying the following:
 - The DML and drug registration are valid
 - The genuineness of the documents provided therein is the responsibility of the applicant.



12.4.Import of Small Quantities of Drugs for Clinical Trial, Test and Analysis

Application for import of small quantities of drugs and biologicals IMP (investigational medicinal products) for clinical trials, can be made by the sponsor / investigators of approved clinical trials sites after obtaining permission from Clinical Studies Committee (Pharmacy Services) on Form VI of Bio-Study Rules, 2017; or for the purpose of test/analysis by the drug manufacturers having Drug Manufacturing License (DML) under Drugs (Import & Export) Rules, 1976 after obtaining Drug Import license ([Form 6](#)) electronically from the relevant field office of DRAP.

However, if such imports contain controlled substances (Narcotic Drugs, Psychotropic Substances and Precursor Chemicals), then additionally an import authorization from the Division of Controlled Drugs is also required.

12.4.1. Documentation requirements for import

Applicants shall apply through online portal (ie.dra.gov.pk.) to the relevant field office (Import & Export section) of DRAP to obtain a clearance certificate/signed invoice for clearance of their consignments from custom ports. Following documents are required to be submitted electronically:-

- 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 principal manufacturer by relevant National Regulatory Authority
- API requirement data, Complete testing protocols/Stability studies protocols.
- Any other document (s) Particularly Required
- Undertaking on stamp paper

12.5.Import of Un-registered/Unavailable Drugs by Hospitals/Institutions:-

Requirements for pre-approval:

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

- Formal application for obtaining pre-approval for import addressed to Additional Director of the relevant field office of DRAP.
- Name, dosage form, quantity of drug, country of origin of drug
- Free Sale Certificate or Certificate of Pharmaceutical Product (CoPP) or any other document which authorized officer shall deem to fulfill the purpose.
- 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 shall also submit a soft copy of data (summary sheet) and each page of the dossier shall be duly signed and stamped.

At the time of arrival of shipment at Customs port,firm shall apply for NOC for Custom clearance along with the following documents:-

- Formal application for obtaining NOC for Custom clearance addressed to Additional Director of the relevant field office of DRAP
- Pre-approval issued by DRAP
- Certificate of analysis or conformance
- Copy of invoice
- Copy of packing list

12.6.Import of Medicines on Donation

Application for import of donation medicines can be made by the Government Institutions, Non-Governmental Organizations (NGOs), or Hospitals after obtaining a prior approval from the DRAP, field offices. When consignment arrives at the port Hospital / institution shall obtain clearance (NOC) from the DRAP field offices.

Requirements for pre-approval:

- 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 donation from donor.
- Registration of NGO/ Hospital/Institution-
- An affidavit of stamp paper containing following conditions: -
 - The drug does not contain any narcotic or psychotropic ingredient;
 - The drug is allowed to be sold freely in the country of its origin;
 - The drug has minimum of six months expiry; and
 - The drug shall not be sold, in any form in the market in Pakistan.

At the time of arrival of shipment at Customs port the firm shall apply for NOC for Custom clearance along with the following documents:-

- Formal application for obtaining NOC for Custom clearance addressed to Additional Director of the relevant field office of DRAP
- Pre-approval issued by DRAP
- Certificate of analysis or conformance
- Copy of invoice
- Copy of packing list

12.7.Import of Medicines for personal use

Online 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. If the applied quantity exceeds 100 doses, approval or rejection will be conveyed after approval from Director QA<, DRAP/Chief Executive Officer, Islamabad. An application for import of drug and biologicals 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 for -importation of drugs and biologicals for personal use:-

- Formal application (in case of physical submission)



- Copy of CNIC of patient and applicant (if applied by the family member)
- List of medicines / drug products to be imported along with name, dosage form, country of origin and quantities.
- A prescription from a registered medical practitioner, (physician, dentist, etc.) also bearing PMC registration number of prescribers.

13. IMPORT OF MEDICAL DEVICES

13.1. Import of medical devices/raw material/components of medical devices:-

A Medical device may be imported subject to the condition that the importer possesses a valid medical device establishment license and medical device enlistment or registration. Raw materials and components of registered/enlisted medical devices may be imported subject to the condition that the importer possesses valid license to manufacture medical devices ([Form 3](#) of the MDR, 2017) and registration/enlistment certificate of a medical device. The applicant shall apply online at ie.dra.gov.pk to obtain clearance certificate from the relevant field office of DRAP.

13.1.1. Documentation requirements for import

- Intimation of arrival of consignment of imported medical device/raw material/component of medical device on [Form -11](#)
- Copy of establishment license to manufacture medical device (in case of import of raw materials and components).
- Copy of enlistment/registration and renewal status of the medical device (if applicable)
- Copy of test report of the medical device/raw material or component of medical device from the manufacturer if applicable,
- Packing list
- Bill of landing (B.L) / Airway bill (A.W.B)
- Invoice
- Deposited challan of applicable fee.
- Undertaking under Rule 25 of the MDR, 2017 on stamp paper.

13.2. Import of Small Quantities of medical devices, components or raw materials for clinical investigation or sample for evaluation etc

Permit for import of small quantities of medical devices, components or raw materials for clinical investigation, examination, test or analysis is issued on [Form 10](#) of MDR, 2017. For this purpose, an application can be submitted on [Form 9](#) to

the Director, MD&MC along with the prescribed fee and record of previous import (if any).

13.3.Import of Un-registered/Unavailable medical devices by Hospitals/Institutions

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

13.3.1. Requirements for pre-approval

An application for pre-approval for import of un-registered/not available medical device by Hospitals/institutions shall be accompanied by the following:-

- Formal application for obtaining pre-approval for import addressed to Additional Director of the relevant field office of DRAP.
- Name, quantity, and country of origin of medical device
- Free Sale Certificate or any other document which authorized officer shall deem to fulfill the purpose.
- Registration of Hospital/Institution
- An affidavit of stamp paper containing following conditions: -
 - i. The import will be made with the prior approval of Licensing Authority under the Rule-24(d)of the MDR, 2017.The medical device will not be sold or distributed in the market;
 - ii. The medical device is on free sale in country of origin.
 - iii. The medical device will be used for therapeutic purpose in the hospital or institutions only and not for the purpose of clinical trial, examination, test or analysis.
 - iv. 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 be the importer under supervision of qualified person.
 - v. The medical device is not enlisted or registered and/or available in Pakistan.
 - vi. The medical device will be provided to patients on ‘No Profit No Loss’ basis.



- vii. Certified that the documents and information provided are genuine and correct and if found at any stage to be misinterpreting or incorrect, it shall lead to legal action under the DRAP Act and the Rules made thereunder.

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

At the time of arrival of shipment at Customs port the applicant shall apply to the relevant field office for NOC for Custom clearance along with the following documents:-

- Formal application for obtaining NOC for Custom clearance addressed to Additional Director of the relevant field office of DRAP
- Pre-approval issued by DRAP
- Copy of invoice
- Copy of packing list

13.4.Import of Medical Devices on Donation

Application for import of donation of medical devices can be made by the Government Institutions, Non-Governmental Organizations (NGOs), or Hospitals after obtaining a prior approval from the DRAP, field offices. When consignment arrives at the port, Hospital / institution shall obtain clearance (NOC) from the DRAP field offices.

13.4.1. Requirements for pre-approval

- Application for the NOC to import medical devices 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 donation from donor.
- Registration of NGO/ Hospital/Institution-
- An affidavit of stamp paper containing following conditions: -
 - The medical device does not contain any narcotic or psychotropic ingredient;
 - The medical device is allowed to be sold freely in the country of its origin;
 - The medical device has minimum of six months expiry; and
 - The medical device shall not be sold, in any form in the market in Pakistan.

At the time of arrival of shipment at Customs port the firm shall apply for NOC for Custom clearance along with the following documents:-

- Formal application for obtaining NOC for Custom clearance addressed to Additional Director of the relevant field office of DRAP
- Pre-approval issued by DRAP
- Bill of Lading/ Airway Bill.
- Copy of invoice
- Copy of packing list

13.5.Import of Medical Devices for personal use

Application for import of medical devices for personal use can be made by the patient or by a family member for the import of unregistered / unavailable medical devices , limited to amount required for personal use only. An application for import of medical device 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 for importation of medical devices for personal use:-

- Copy of CNIC of patient and applicant (if applied by the family member)
- List of medical devices to be imported along with name, country of origin and quantities.
- A prescription from a registered medical practitioner, (physician, dentist, etc.) also bearing PMC registration number of prescribers (if required).

14.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 and raw materials 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.

An importer has to apply for obtaining clearance certificate for each consignment on the online portal ie.dra.gov.pk accompanying the following documents:

For raw materials including Active ingredients, excipients, packaging and labeling materials etc,:

- Intimation of arrival of consignment of imported alternative medicine / health product on [Form -8](#)



- Copy of Valid D.I.L ([Form 5](#))
- Copy of Enlistment certificate (Form 6)
- Copy of Product enlistment certificate Batch Certification ([Form-7](#))
- Certificate of Analysis
- Monograph (latest testing reference) USP/BP/EU/JP etc., of raw material (if applicable / required)
- Valid manufacturing license and GMP Certificate of the principal manufacturer by respective National Regulatory Authority
- Packing list
- Bill of landing (B.L) / Airway bill (A.W.B)
- Invoice
- Percentage (%) remaining shelf life (as per IGM date)
- 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.
- Undertaking on stamp paper specifying the following:
 - The genuineness of the documents provided therein is the responsibility of the applicant.

For Finished alternative medicines and health & OTC products:

- Intimation regarding Import on Form -1
- Intimation of arrival of consignment of imported alternative medicine / Health & OTC Product on Form -8
- Copy of enlistment
- 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 applicable)
- Packing list
- Bill of landing (B.L) / Airway bill (A.W.B)
- Invoice
- Percentage (%) of remaining shelf life (as per IGM date)
- Deposited challan of applicable fee.



- Undertaking on stamp paper specifying the following:
 - Form 6 and Form 7 are valid
 - The genuineness of the documents provided therein is the responsibility of the applicant.



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 apply on online portal for export of therapeutic goods along with all requisite documents and obtain an NOC from the respective field office of DRAP before exporting any consignment.

15.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 registered products of their allied licensed manufacturers after an NOC to export drug from the respective field office of DRAP.

Other than finished drugs and biologicals can also be exported, for which a Drug Export License (Form 9) and an NOC from respective field office of DRAP is required.

15.1.Drug Export License (D.E.L)

An application for issuance of Drug Export License for other than finished drugs and biologicals can be made 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 and biologicals of one 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 applicant is required 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.

15.2.Documentation requirements for issuance of NOC for Export of other than finished drugs:-

Exporters having valid drug export license shall apply online on ie.dra.gov.pk to obtain an NOC for export of than finished drugs and biologicals from the relevant field office (Import & Export section) of DRAP. Following documents are required to be submitted:-

- Drugs Sale License/ Drugs Manufacturing License with Renewal Status (if applicable)
- Copy of Valid D.E.L
- Batch certificate on [Form-7](#)
- Certificate of Analysis
- Valid GMP Certificate of the exporting firm/ Last Panel Inspection Report



- Packing list
- Export Order
- Invoice
- Deposited challan of the prescribed fee
- In case of export of controlled substance, an export authorization from the Division of Controlled Drugs is also required.

15.3.Documentation requirements for issuance of NOC for Export of finished drugs and biologicals

Exporters shall apply online on ie.dra.gov.pk to obtain an NOC for export of drugs and biologicals from the relevant field office (Import & Export section) of DRAP. Following documents are required to be submitted:-

- Drugs Sale License/ Drugs Manufacturing License with Renewal Status (if applicable)
- Copy of drug Registration & Renewal Status (if applicable)
- Batch certificate on [Form-7](#)
- Certificate of Analysis
- GMP(Good manufacturing practices) Certificate/ last inspection report
- Packing list
- Export Order
- Invoice
- Deposited challan of the prescribed fee
- In case of Drug Sale License holder, an NOC from the manufacturer for export of its products
- In case of export of controlled substance, an export authorization from the Division of Controlled Drugs is also required.

15.4.Export of drugs for the purpose of clinical trial, examination, test and analysis

An application for permission to export small quantities of drugs and biologicals for the purpose of clinical trial, examination, test or analysis can be made online on ie.dra.gov.pk by a licensed manufacturer having DML, along with the following documents;

- [Form 12](#)
- Document specifying the purpose and quantity to be exported
- Invoice



- Packing list
- Certificate of analysis (if applicable)
- Deposited challan of applicable fee

The drugs / biologicals for clinical trials, examination, test & analysis purpose can then be exported after issuance of NOC from respective field office of DRAP.

15.5.Export of drugs for personal use

An application for export of drugs 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 for export of drugs and biologicals for personal use:-

- Copy of Pakistani CNIC or passport of patient and applicant (if applied by family member)
- List of medicines / drug products to be exported along with name, dosage form, strength and quantities.
- A prescription from a registered medical practitioner, (physician, dentist, etc.) also bearing PMC registration number of prescribers.

The drugs / biologicals for personal use then can be exported / carried abroad after issuance of NOC from respective field office of DRAP.

16.EXPORT OF MEDICAL DEVICES

Medical Devices having enlistment/registration from Medical Devices Division of DRAP can be exported from Pakistan. Licensed exporters are required to apply online on ie.dra.gov.pk to obtain an NOC from the respective field office of DRAP. Following general conditions are required to be met for export of medical devices:

- Export permit issued on [Form 13](#) of MDR 2017
- Exporter is an establishment license holder
- The medical device to be exported is enlisted/registered with MDB of DRAP
- Export order

16.1.Export permit

An application for export permit for enlisted/registered medical devices can be made online at ie.dra.gov.pk by an establishment license holder on [Form 12](#) of the

MDR, 2017 accompanied by applicable fee. An export permit is issued on [Form 13](#) and will be valid for a period of three years unless it is suspended or cancelled earlier. After issuance of Form 13, an exporter is required to obtain an NOC from respective field office of DRAP for which following documents are required:

- Establishment license with Renewal Status (if applicable)
- Copy of Valid export permit ([Form 13](#))
- Copy of enlistment/Registration of medical device & Renewal Status
- Certificate of Analysis
- Packing list
- Export Order
- Invoice
- Deposited challan of the prescribed fee

16.2.Export of medical devices for the purpose of clinical investigation, examination, test and analysis:

An application for issuance of export permit to export small quantities of medical devices including those the export of which is otherwise without enlistment for the purpose of clinical investigation, examination, test or analysis can be made online on ie.dra.gov.pk by a establishment license holder of medical devices (Form 14) along with the applicable fee. Export permit is issued on Form 15 and is valid for a period of three years unless earlier suspended or cancelled.

16.3.Export of medical devices for personal use

An application for export of medical devices 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 for exports of medical devices for personal use:-

- Copy of Pakistani CNIC or passport of patient and applicant (if applied by family member)
- List of medical device to be exported along with name and quantities.
- A prescription from a registered medical practitioner, (physician, dentist, etc.) also bearing PMC registration number of prescribers (if required).

Medical devices for personal use then can be exported / carried abroad after issuance of NOC from DRAP.



17. EXPORT OF ALTERNATIVE MEDICINES AND HEALTH PRODUCTS

Manufacturers of Health & OTC products and Drug Sale license holders (for enlisted products of their allied enlisted manufacturers) can export health & OTC products, by submitting an online application on ie.dra.gov.pk. The application should accompany the following documents:-

- Enlistment certificate of manufacturer
- Copy of Valid D.E.L for other than Finished Drugs (Form 9)
- Copy of product enlistment certificate
- Batch certificate on [Form-7](#)
- Certificate of Analysis
- Packing list
- Export Order
- Invoice
- Deposited challan of the applicable fee
- In case of Drug Sale License holder, an NOC from the manufacturer for export of its products.

Health & OTC products then can be exported after issuance of NOC from respective field office of DRAP.

18. STORAGE FACILITIES

Many pharmaceutical products tend to degrade during storage and some need to be stored under specified conditions such as 2–8°C i.e. cold storage. All Customs ports 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. 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.



19. REFERENCES

- 19.1. The DRAP Act 2012.
- 19.2. The Drug Act 1976.
- 19.3. The Drugs (Import & Export) Rules, 1976
- 19.4. The Medical Devices Rules, 2017
- 19.5. The Alternative Medicines and Health products Rules, 2014.
- 19.6. WHO guidelines on import procedures for medical products



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