PHARMACY AND MEDICINES REGULATORY AUTHORITY

Quality Medicines for Malawi

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GUIDANCE ON IMPORTATION AND EXPORTATION OF MEDICINAL PRODUCTS AND ACTIVE PHARMACEUTICAL INGREDIENTS

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ABBREVIATIONS

API	Active Pharmaceutical Ingredient
CD	Controlled Drug
COA	Certificate of Analysis
COPP	Certificate of Pharmaceutical Product
GMP	Good Manufacturing Practices
IMP	Investigational Medicinal Products
INN	International Non-Proprietary Name
MAH	Marketing Authorization Holder
MOH	Ministry of Health
PIL	Patient Information Leaflet
PIC/S	Pharmaceutical Inspection Cooperation Scheme
PMRA	Pharmacy and Medicines Regulatory Authority
SADC	Southern Africa Development Community
SRA	Stringent Regulatory Authority
USFDA	United Stated Food and Drug Administration
WHO	World Health Organization

1- INTRODUCTION

This guiding document is for those intending to import and/or export active pharmaceutical ingredients and medicinal products into or outside Malawi respectively. The document describes the requirements, processes and details the steps involved in importation and exportation of medicines and active pharmaceutical ingredients and should be read together with the relevant parts of the Pharmacy and Medicines Regulatory Authority Act No.9 of 2019 and relevant Regulations. The guiding document is aimed at standardizing the manner in which medicines and active pharmaceutical ingredients are imported and/or exported. It is the Authority's considered view that through the implementation of these guidelines, patients and the general public at large shall be protected from use of products that fall short of the prescribed medicines' standards for quality, safety and efficacy.

2- INTERPRETATION OF TERMS USED IN THIS GUIDING DOCUMENT

2.1 Active Pharmaceutical Ingredients: Means any substance or mixture of substances intended to be used in the manufacture of medicine and that, when used in the production of a pharmaceutical product, becomes an active ingredient of the pharmaceutical product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body

2.2 Authority: Means the Pharmacy and Medicines Regulatory Authority (PMRA) of Malawi.

2.3 Authorized Applicant: Means a pharmacist registered by the Authority in whose name the pharmaceutical business is registered or operates.

2.4 Authorized importer: Means a person authorized to import medicines as defined in the PMRA Act and Regulations.

2.5 Controlled substances: Means narcotic drugs and psychotropic substances under International Narcotic Control Board (INCB).

2.6 Committed for registration: Means the application for registration of the product has been filed and relevant fees paid to the Authority.

2.7 Emergency use: Means use of unregistered medicines during a declared public health emergency involving heightened risk of affliction or attack on the health of the general public.

2.8 Importation: Means the act of bringing or causing any goods (in this case medicines) to be brought into a national territory.

2.9 Manufacture: Includes all operations of purchase of materials and products, production, quality control, release, storage, shipment of finished products, and related controls.

2.10 Market Authorization Holder: Means a pharmaceutical company which is given an authority to market a pharmaceutical product or a set of pharmaceutical product by the Authority.

2.11 Narcotic drug: Also referred to as a controlled substance is any substance listed in Schedules I and II of the 1961 Single Convention on Narcotic drugs as amended by the 1972 Protocol, whether natural or synthetic.

2.12 Parallel importation: Means importation of registered pharmaceutical product into a country without the knowledge of marketing authorization holder (MAH).

2.13 Pharmaceutical product: Means any medicine intended for human or veterinary use, presented in its finished dosage form, that is subject to control by pharmaceutical legislation.

2.14 Product: Means finished pharmaceutical product, a medicine or active pharmaceutical ingredient.

2.15 Permit: Means an import/export authorization granted by the Authority for import or export of medicines or active pharmaceutical ingredients.

2.16 Product licence: Means an official document issued by the competent medicine regulatory authority for the purpose of marketing or free distribution of a product.

2.17 Promotion: refers to all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

2.18 Psychotropic substance: Also referred to as a controlled substance is any substance whether natural or synthetic listed in Schedules I, II, III or IV of the 1971 Convention on psychotropic substances.

2.19 Registration: Means any statutory system of approval required at national level as a precondition for introducing a pharmaceutical product on the market.

2.20 Zazibona: A Collaborative Medicines Registration Initiative in SADC.

3- PART ONE

IMPORTATION OF MEDICINAL PRODUCTS AND ACTIVE PHARMACEUTICAL INGREDIENTS

3.1. CATEGORIES OF AUTHORISED IMPORTERS

3.1.1. Government and Non- Governmental Organizations or similar institutions including faith-based organizations.

3.1.2. Pharmaceutical wholesalers.

3.1.3. Principal investigator of a registered clinical trial.

3.1.4. Recipients of donations.

3.1.4.1. A pharmacy or veterinary shop importing medicines for specific patients or animal.
3.1.4.2. Pharmaceutical manufacturers

3.2. TYPES OF IMPORT PERMITS

3.2.1. Commercial medicine import permit: This type of permit covers pharmaceutical products being imported for commercial purposes.

3.2.2. Narcotic, psychotropic import permit: This type of permit covers importation of narcotic and psychotropic imported for commercial purposes.

3.2.3. Active Pharmaceutical ingredient import permit: This type of permit covers importation of active pharmaceutical ingredient for local production of medicines.

3.2.4. Import permit for medicines for specific patient: This type of permit covers importation of medicines for personal use.

3.2.5. Investigation medicinal product import permit: This type of permit covers importation of investigational medicinal products (IMPs) and auxiliary medicines being imported for the approved clinical trial.

3.2.6. Medicine registration samples import permit: This permit covers importation of medicine samples for assessment, registration, investigation and quality tests.

3.2.7. Donation import permit: This type of permit covers importation of donated medicines to institutions or organizations in the country.

3.2.8. Promotional material import permit: This type of permit serves to facilitate importation of medicines for health-related information promotional purposes.

3.3. GENERAL REQUIREMENTS FOR IMPORTATION

3.3.1. All medicines to be imported must be registered and retained on the register by PMRA.

3.3.2. All importers should declare the correct and true value of the consignment that will be imported and any departure from the truth will be punishable by the Authority.

3.3.3. Correct product details should be submitted on the application and should be exactly as the ones registered by PMRA.

3.3.4. All importation of medicines and(or) active pharmaceutical ingredients must be done by importers whose premises are duly registered or recognized by PMRA.

3.3.5. All shipments of medicine or active pharmaceutical ingredient consignments should be dispatched from the country of origin only upon receipt of import permit by the importer and in line with the approved list.

3.3.6. Applications for import permit should only be signed by an authorized applicant.

3.3.7. Separate import permit applications should be submitted for each category of product (active raw materials, registered medicines, unregistered medicines and controlled drugs).

3.3.8. All imported medicines and(or) active pharmaceutical ingredient should adhere to the following minimum labelling requirements;

3.3.8.1. The information printed on labels must be indelible, engraved or embossed on a primary and secondary container;

3.3.8.2. The immediate outer packaging of the medicine or active pharmaceutical ingredient should be clearly labelled in English;

3.3.8.3. The trade or brand name where applicable should be stated;

3.3.8.4. The International Non-Proprietary Name (INN, Generic name) should be clearly stated;

3.3.8.5. State quantities of each active pharmaceutical ingredients (API) in the given formulation or quantities of the raw material;

3.3.8.6. Date of manufacture and expiry or retest date in case active raw materials;

3.3.8.7. Batch or Lot number;

3.3.8.8. Storage conditions;

3.3.8.9. Name and address of manufacturer;

3.3.8.10. Registration number of the product issued by PMRA in both outer and inner package of the product(s) where applicable;

3.3.8.11. Enclosed and accompanying literature must be in English;

3.3.8.12. The specification of the API is given according to officially recognized pharmacopoeia, where applicable.

3.3.9. Import/export permit processing attracts a fee of 1.5% for registered and 6% for unregistered medicine of the total invoice value. These fees are subject to change from time to time

3.3.10. Upon issuance of import/export authorization by the Authority, the importer/exporter is expected to retain such records for a period of five (5) years from the date of importation/exportation. Such storage can be in either form of hard copy or electronic. Stored import/export records should be easily accessible and availed for review to the Authority's inspector/officers for any post-import/export audit or investigations.

3.3.11. The port of entry/exit of products should be through the gazette or designated port of entry/in-land depot.

3.3.12. Before issuance of any of the permits in part 1.2 above, the Authority may wish to ascertain the rational use of the product. In this regard, the Authority may undertake audit of the importing entity and the utilization of the same including audits for third parties who might have been sold or have requested for such a supply. Where the Authority is not satisfied with the audit findings, the Authority may decline issuance of the permit.

3.4. PROCEDURE FOR IMPORTATION OF MEDICINAL PRODUCTS AND ACTIVE PHARMACEUTICAL INGREDIENTS

3.4.1. Authorized importers intending to import medicines or active pharmaceutical ingredients should apply to the Director General, PMRA by filling in the application form/cover letter as prescribed under Annex 1 of this guiding document in both hard and electronic copies.

3.4.2. The application form/cover letter should be accompanied by the following;

3.4.2.1. A Certificate of Analysis (CoA) for each product.

3.4.2.2. One original commercial invoice from the marketing authorization holder or authorized supplier(s) of the product(s).

3.4.3. The original Commercial invoices should state for each medicinal product to be imported, the following;

3.4.3.1. Commercial invoice number and date.

3.4.3.2. Name of the supplier.

3.4.3.3. Name of the manufacturer.

3.4.3.4. Country of origin.

3.4.3.5. Trade or Brand or proprietary name.

3.4.3.6. The International Non Proprietary name (generic name) of the drug and its strength.

3.4.3.7. In the case of the product containing more than one active ingredient, the name and strength of each active ingredient should be stated.

3.4.3.8. The pharmacopoeia specification of the ingredient such as BP, USP.

3.4.3.9. The quantity to be imported/exported for each medicine, its unit value, total value in acceptable currency.

3.4.3.10. Batch/Lot number for each product.

3.4.3.11. Manufacturing and expiring or retest date in case of active ingredients.

3.4.3.12. Signature and stamp of the supplier.

3.4.4. The application form/cover letter (Annex 1) should be stamped and signed by authorized applicant of the importer before submission to PMRA.

3.4.5. The import permit will be valid for six (6) months, not transferable to any other person and may be extended for such a period not exceeding three (3) months upon successful application to the Authority.

3.5. PROCESSING OF IMPORT PERMIT APPLICATIONS

3.5.1. Upon receipt of the application as specified in part 3.4 above, PMRA will conduct assessment to verify whether the requirements have been fulfilled.

3.5.2. If the application meets the prescribed requirements, the applicant will be required to pay applicable import permit fees as stipulated in the current Pharmacy and Medicines Regulatory Authority (Fee and Forms) Regulations and the Authority will issue an import permit.

3.5.3. If the application does not meet the importation requirements, the application will be rejected. In the case that the application has been rejected, the applicant will be issued a rejection letter as set out in Annex 2 stating clearly reason(s) for rejection.

3.5.4. Regulatory processing time for import permit application is ten (10) working days.

3.6. SPECIAL IMPORTATION REQUIREMENTS

The same application requirements and procedures as prescribed under section 3.4 and 5.5 will apply. However, in some special circumstances the following requirements will be applicable:

3.6.1. COMMERCIAL IMPORT PERMIT FOR UNREGISTERED MEDICINAL PRODUCTS

Unregistered medicinal products requested for importation will be issued an import permit only if they meet the following criteria: -

3.6.1.1. An applicant has applied for a special permit stating reasons backed by supporting documents for importing unregistered medicines.

3.6.1.2. The medicinal product has registered therapeutic/pharmaceutical equivalent or alternative product with PMRA but verified not to have been available in Malawi or there are no registered pharmaceutical equivalents/alternatives at the time the application is filed to the Authority.

3.6.1.3. The medicinal product comes from a PMRA or Pharmaceutical Inspection Cooperation Scheme (PIC/S) or any Stringent Regulatory Authority (SRA) or World Health Organization (WHO) Good Manufacturing Practice (GMP) certified manufacturing site(s).

3.6.1.4. Provision of an acceptable Certificate of Analysis (CoA) from the manufacturer for each product batch.

3.6.1.5. Provision of evidence that the product is registered in any SADC country through the ZAZIBONA initiative or is authorized by USFDA or EMA or in any country with SRA or the product is WHO prequalified.

3.6.1.6. Provision of Certificate of Pharmaceutical Product (CoPP), where applicable.

3.6.1.7. Provision of Pharmaceutical Wholesale Pharmacy/supplier licence or certification of the exporting firm issued by their National Medicines Regulatory Authority in the exporting country, where applicable.

3.6.1.8. Medicinal products committed for registration will be treated as unregistered medicines and will have to meet the above requirements if intended to be imported into the country.

3.6.2. COMMERCIAL IMPORT PERMIT FOR CONTROLLED DRUGS

3.6.2.1. For medicines that are narcotic or psychotropic as per International Narcotic Control board list and scheduled as controlled drugs (CD) by PMRA, the applicant will be required to apply for a narcotic or psychotropic license before applying for an import permit.

3.6.2.2. Procedure for application for narcotic/psychotropic license will be as stipulated in the guiding document for control of narcotics.

3.7. INVESTIGATIONAL MEDICINAL PRODUCT IMPORT PERMIT

3.7.1. Applications for importation of investigational medicinal products to be used in a clinical trial should be made by the pharmacist of record for the trial.

3.7.2. Such application should be accompanied by supporting documents as stipulated in the guidelines for authorization of importation of Investigational Medicinal Product (IMP) by PMRA.

3.8. EMERGENCY USE AUTHORISATION PERMIT

3.8.1. Importation of medicinal products in emergency situation and in compliance with section 62(e) of the PMRA Act, PMRA will reserve discretionary powers to waive product licensing requirements in respect of consignments of medicinal products imported in response to emergency situations.

3.8.2. The application should meet the following requirements;

3.8.2.1. Provision of evidence that the Ministry of Health (MOH) recommended the use of the product in Malawi.

3.8.2.2. Cover letter giving reasons for importation from the authorized applicant.

3.8.3. The application should fulfil the requirements as stated in 3.3 except 3.3.1

3.9. IMPORT PERMIT FOR MEDICINES FOR SPECIFIC PATIENTS/ANIMALS

3.9.1. This type of permit caters for person or patient who intends to import a medicine prescribed by a physician under his care or for returning patients who have been receiving treatment abroad or are in long term treatment and must continue to get refills based on their doctor's review. The quantity of the medicine in this type of application is based on the prescription but limited to six (6) months' supply.

3.9.2. Application for importation of medicine(s) for personal use should be facilitated by the authorized applicants and should be accompanied by the following;

3.9.3. Cover letter giving reasons for importation from the authorized applicant should be submitted to the Authority.

3.9.4. A valid prescription from a practicing medical practitioner, dentist, veterinary surgeon or any other authorized practitioner.

3.9.5. Commercial invoice.

3.10. PROMOTIONAL MATERIAL IMPORT PERMIT

3.10.1. This type of permit serves to facilitate importation of medicines for health-related information promotional purposes such as medical or physician samples, scientific conferences, healthcare workers training, product detailing items with health-related information, health-related scientific exhibitions and fairs, tournament and sport. The permit serves to offer temporary entry of medicines for the above stated events. In such situations, this should be declared to the Authority before entry and the same served before exit.

3.10.2. Application for Importation of promotional material should be accompanied meet the following criteria:

3.10.3. Proforma invoice/non-commercial invoice/packing list itemizing the products being imported, their Batch/lot numbers (where applicable);

3.10.4. In case of exhibitions/fairs, a letter confirming allocation/participation of an entity in that exhibition/fair;

3.10.5. Samples should have been registered by the Authority or as may be determined by the Authority.

3.11. **FOR IMPORTATION OF PHYSICIAN SAMPLES OR FREE MEDICAL SAMPLES FOR MARKET TESTING;**

3.11.1. Samples should be` registered by the Authority.

3.11.2. Samples should bear a label printed "Free sample – Not for sale" in bold letters.

3.11.3. Samples should be in a small pack that is adequate for one patient as opposed to a commercial pack.

3.11.4. Applications not meeting the above criteria should be treated accordingly as applications for (un)registered medicines.

3.12. DONATION IMPORT PERMIT

Applications for importation of donated medicinal products will be dealt with in accordance with the Authority's donation guidelines.

3.13. REGISTRATION SAMPLES IMPORT PERMIT

3.13.1. This permit covers importation of medicine samples being imported for assessment, registration, investigation and quality tests. The quantity is limited to either quality laboratory test requirements, the Authority's samples for assessment requirements, or any other quantity that may be preferred by the Pharmacy and Medicines Regulatory Authority. The following are the requirements;

3.13.2. Proforma/commercial invoice/non-commercial invoice detailing the medicines are for product assessment/registration/quality tests;

3.13.3. Wholesale dealer's license of the authorized local distributor or a letter appointing a local distributor;

3.13.4. Certificate of analysis/conformity.

3.14. PARALLEL IMPORTATION OF MEDICINAL PRODUCTS

The Authority shall not allow parallel importation of medicinal products.

3.15. INSPECTION OF IMPORTED MEDICINAL PRODUCTS OR ACTIVE PHARMACEUTICAL INGREDIENT AT PORTS OF ENTRY/IN-LAND DEPOT.

3.15.1. All medicines will be cleared at in-land port of entry.

3.15.2. The importer or their nominated clearing agents will be notified of arrival of the consignment by airline/truck/vehicle at designated in-land port.

3.15.3. Where medicinal products or active pharmaceutical ingredient are detected, such an entry/declaration/consignment should be routed/assigned to the Authority for inspection or verification and advise to the customs authority officials on whether to release or not to release the consignment. This should be done in the designated systems in place at the time such as Asycuda World or any other system determined as appropriate by the Authority in agreement with the other port users.

3.15.4. Consignment inspection and verification is two phased:

3.15.5. Phase one is document verification.

This will entail the verification of the following particulars or documents;

3.15.5.1. Commercial Invoice and the declared value in relation to what was declared during permit requisition;

3.15.5.2. Importer: This should be the authorized Local distributor or local manufacturer (in case of active raw materials) any authorized importer;

3.15.5.3. The imported products in relation to Authority's import permit approval;

3.15.5.4. Certificate of analysis/Conformity (COA/CoC) of the product;

3.15.5.5. Quantities of products imported versus those authorized during permit acquisition;

3.15.5.6. Alignment of the particulars of the entry (declaration) to those in permit, airway bill/bill of landing;

3.15.6. Phase two is consignment inspection.

This will include the following activities;

3.15.6.1. Actual product presentation through organoleptic examination;

3.15.6.2. Products physically present versus those on the invoice and permit;

3.15.6.3. Physical product label claim versus that on the invoice & permit;

3.15.6.4. Product labelling characteristics as declared to the Authority during product registration (dossiers) and as presently secured on the Authority's database;

3.15.6.5. Storage conditions as per the declared climatic zones;

3.15.6.6. Patient information leaflet (PIL);

3.15.6.7. Manufacturing site in country of origin;

3.15.6.8. Quantities of the products imported versus those allowed in the permit and those on invoice;

3.15.6.9. Batch numbers, manufacture and expiry dates of the products;

3.15.6.10. Minilab tests based on a risk-based approach;

3.15.6.11. Spelling errors, low-quality printing, volume disparities in ampoules and other defects may be signs of a substandard or falsified product. The external package should be intact and should not show any signs of damages or infiltrations that may change the inner content. If such is detected during port inspections and verifications, further regulatory actions may be taken.

3.15.6.12. During inspection, if an inspector determines more clarity is needed as to ascertain quality, safety and efficacy of a product, he/she should draw sample in line with the sampling procedure of the Authority, for minilab tests or full laboratory tests and investigations.

3.15.6.13. Consequently, he/she should quarantine the consignment in appropriate warehouse as determined appropriate by the Authority. The same should be communicated to the customs officers and the owner or their nominated clearing agent in the system as either the consignment has been placed on-hold, or queried or to be released under quarantine. The consignment will await the minilab tests or laboratory test report or investigation report for subsequent decision.

3.15.6.14. If the inspection outcome is successful, the inspector may remove hold (default hold) and signal a No-Objection status for release of the consignment to the custom officials.

PART TWO

3 EXPORTATION OF MEDICINAL PRODUCTS AND ACTIVE PHARMACEUTICAL INGRIDIENTS

4.1 CATEGORIES OF EXPORTERS:

4.1.1 Registered local pharmaceutical manufacturers.

4.1.2 Registered pharmaceutical wholesalers.

4.1.3 Principal Investigators of approved clinical trial with PMRA.

4.1.4 Individuals exporting medicines for personal use.

4.1.5 Government and Non- Governmental Organizations.

4.2 GENERAL REQUIREMENTS FOR EXPORTATIONS

4.2.1 As required by the law, a person who intends to export pharmaceutical products is required to have a valid export permit issued by the Authority.

4.2.2 Provision of evidence that the product was sourced legally.

4.2.3 All pharmaceutical products to be exported must come from authorized premises registered with the Authority.

4.2.4 All pharmaceutical products should have minimum labelling requirements as prescribed in 3.3.8

4.2.5 All requirements for importation stated in Section 3.3 will apply for exportation.

4.3 PROCEDURE FOR EXPORTATION OF MEDICINAL PRODUCTS AND ACTIVE PHARMACEUTICAL INGRIDIENTS

4.3.1 Authorized exporter intending to export products should apply to the Director General, PMRA by filling in the application form as prescribed under Annex 3 of this guiding document in both hard and electronic copies.

4.3.2 The application form should be accompanied by one original commercial invoice.

4.3.3 The Original commercial invoices should state for each product to be exported as in 1.4.3 above.

4.3.4 In situations where a local product is not manufactured for the local market, either or some of the below list of certificates may be requested by the Authority:

4.3.4.1 Import authorization from the foreign national medicines regulatory authority (NMRA) or in case of controlled drugs (narcotics, psychotropic), an import permit from a NMRA of an importing country. The postal address, physical address, email address and/or telephone number of the NMRA of the importing country have to be clearly indicated.

4.4 INDIVIDUALS EXPORTING MEDICINES FOR PERSONAL USE (PRESCRIPTION MEDICINES EXPORT PERMIT)

4.4.1 This type of permit caters for persons who intend to export a medicine prescribed by a physician for their patient who is abroad or for travelling patients who have been receiving treatment locally or are in long term treatment and must continue to get refills whilst abroad based on their doctor's review. The quantity of the medicine in this type of application is based on the prescription and in compliance with the regulations of the destination country.

4.4.2 Application for exportation of medicine(s) for personal use should be facilitated by the authorized applicants or relatives of the patient and should be accompanied by the following;

4.4.2.1 Cover letter giving reasons for exportation from the authorized applicant or relative of the patient should be submitted to the Authority;

4.4.2.2 A valid prescription from a practicing medical practitioner, dentist, veterinary surgeon or any other authorized practitioner;

4.4.2.3 Purchase receipt or provide evidence that the medicine was sourced from registered premises.

4.5 PROCESSING OF EXPORT PERMIT APPLICATIONS FOR PRODUCTS

4.5.1 Upon receiving the application as specified above, PMRA will verify whether the requirements have been fulfilled.

4.5.2 After being satisfied by the information submitted, an export permit will be issued.

4.5.3 An application will be rejected if it does not meet any of the exportation requirements. An applicant will be given a rejection letter (Annex 2) stating clearly reason(s) thereof.

4.5.4 The regulatory processing time for export permits will be ten (10) working days.

4.5.5 Export permit will be valid for three (3) months for individual use and six (6) months for commercial use. The export permit will not transferable to any other person and may be extended for such a period not exceeding one month for individual use and three (3) months for commercial use upon successful application to the Authority.

Annex 1: Import Permit Cover Letter/Application Form

Company logo/letter head
To: Director General
Pharmacy and Medicines Regulatory Authority
P.O Box 30241
Capital City
LILONGWE 3

Date:

Dear Sir/Madam,

APPLICATION FOR IMPORTATION OF MEDICINAL PRODUCTS/RAW MATERIALS

I/We…….....
of (postal address) …… undertaking the business of Pharmaceutical Wholesale/manufacturing/Other (Specify)……wi th premises registration No.: PMRA/xx/yy……hereby apply for importation permit for medicines/active pharmaceutical ingredient into Malawi through ……..port of entry/in-land depot.

List of products as in table below;

No.	**Brand Name**	**Generic Name**	**Name and country of Manufacturer**	**Batch /Lot No.**	**Pack Size**	**Qty.**	**PMRA Reg. No.**
		SAMPLE FORMAT FOR USE AT EACH SUBMISSION FOR IMPORT AUTHORISATION BY PMRA					

Attached overleaf is a list of registered/unregistered medicines (if not registered, please give reasons for importation)

Reasons……
……
……

Attached herewith the proforma invoice No... ... ... of (date)... ... ...

Declaration:
I certify that the information provided in the application form and proforma invoice is true and correct.

Name & Signature of Authorised applicant.....

Pharmacist Registration No.: ……..

Stamp & date……..

Proforma Invoice No.:…… Dated:……

No.	Brand **Name**	**Generic Name**	**Name and country of Manufacturer**	**Batch No.**	**Pack Size**	**Qty.**	**PMRA Reg. No.**

Annex 2: Import Permit Rejection Form

Quality Medicines for Malawi

Ref. No.: **PMRA- XXXX** 00 March 2020
Ref. No.: XXX

Address of Pharmaceutical Business
XXXXXXXX
XXXXXXX

ATTENTION: Name

Dear Sir/Madam,

REJECTION OF IMPORTATION/EXPORTATION OF MEDICINAL PRODUCTS

Reference is made to your application dated …… with proforma invoice No.:…….. Dated …… on importation/exportation of the following products. Find below the reason/s for rejection.

No.	Brand Name	Generic Name	Reason/s for rejection
1			
2			

Approving Authority

DIRECTOR GENERAL

Annex 3 Export Permit Cover Letter/Application Form

Quality Medicines for Malawi

COMPANY LOGO/LETTER HEAD

To: Director General
Pharmacy and Medicines Regulatory Authority
P.O Box 30241
Capital City
LILONGWE 3

Dear Sir/Madam,

APPLICATION FOR EXPORTATION OF MEDICINAL PRODUCTS

I/We …….. …….. undertaking the business of Wholesale/Pharmaceutical manufacturing/Other (Specify)…….. with export permit number …….. issued on…….. …….. Name of Pharmacist/authorized applicant in charge of the business……Registration Number…….. Hereby apply for export permit of Medicinal products to:

Consignee……Physical address/Location of business……..Postal address…….. city name……..
Country name……

Consignment content details:

No.	Brand Name	Generic Name	Name and country of Manufacturer	Batch No.	Pack Size	Qty.	Expiry Date

		SAMPLE FORMAT FOR USE AT EACH SUBMISSION FOR IMPORT AUTHORISATION BY PMRA					

Attached overleaf is the list of products.
Attached herewith is the Proforma Invoice No……of (date)... ... ...

Declaration:
I certify that the information provided in the application form and proforma invoice are true and correct.

Name & Signature of Applicant..... Stamp……..
Date:……..

Proforma Invoice No.:…… Dated:……..