GOVERNMENT NOTICE NO. 94

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY AUTHORITY (IMPORT) REGULATIONS, 2026

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IN EXERCISE of powers conferred by section 129 as read together with section 58 (4) of the Act, I, MADALITSO BALOYI, the Minister of Health and Sanitation, on recommendation of the Pharmacy and Medicines Regulatory Authority, make the following Regulations—

PART I

PRELIMINARY

Citation

1. These Regulations may be cited as the Pharmacy and Medicines Regulatory Authority (Import) Regulations, 2026.

Interpretation

2. In these Regulations, unless the context otherwise requires—

"free medical samples" means medicines and allied substances used for promotional purposes; and

"import permit" means a provisional permit issued, per consignment, by the Authority to an importer authorizing him to bring medicines and allied substances into Malawi.

Part II

Importation of Medicines and allied Substances

Requirements for importer of medicines and allied substances

3.—(1) A person shall import medicines if the person—

(*a*) is a pharmacist registered by the Authority and manager of a pharmaceutical business;

(*b*) holds a valid wholesale licence issued under the Act;

(*c*) holds an import permit issued under the Act; and

(*d*) satisfies any conditions set by the Authority.

(2) A person shall import allied substances if the person —

(*a*) holds a valid wholesale licence issued under the Act;

(*b*) holds an import permit issued under the Act; and

(*c*) satisfies any conditions set by the Authority.

(3) Notwithstanding sub-regulation (1) and (2), a person shall, through a pharmacy or veterinary shop, with approval from the Authority, import a medicine or allied substance if the person—

(*a*) is a veterinary practitioner and is importing medicines or allied substances for an animal;

(*b*) is a medical practitioner and is importing medicines or allied substances for his patient; or

(*c*) is a dentist and is importing medicines or allied substances for his patient.

(4) A person shall not import an active pharmaceutical ingredient unless he is a licensed pharmaceutical manufacturer.

Application for importation of unregistered medicines and allied substances

4.—(1) The Authority may, upon request by an authorized importer and in the interest of the public or in an emergency, approve the importation of unregistered medicines and allied substances on such conditions as the Authority may deem fit.

(2) A person shall submit an application for importation of unregistered medicine and allied substance in Form 1EI, prescribed in the *First Schedule*, to the Authority and it shall be accompanied by—

(*a*) evidence, which may be in the form of a local purchase order, that the product is required in the country,

(*b*) a certificate of analysis of all the batches to be imported;

(*c*) a certificate of good manufacturing practices, issued by the Authority or Stringent Regulatory Authority or World Health Organisation or Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme or relevant International Standards Organisation, in the case of allied substances;

(*d*) where possible, a certificate of pharmaceutical product; and

(*e*) a copy of the final invoice, numbered and dated, duly filled and signed by the responsible officer of the business.

(3) Subject to sub-regulation (2)(*e*), the final invoice shall indicate the—

(*a*) name and address of the manufacturer of each product;

(*b*) name and address of the supplier where possible;

(*c*) trade or proprietary name of each product;

(*d*) international non-proprietary name;

(*e*) drug and strength of each product;

(*f*) name and strength of each product, in the case of a product containing more than one active ingredient;

(*g*) specification of the ingredient according to officially recognised pharmacopoeia;

(*h*) quantity, pack size, unit value, total value in convertible currency;

(*i*) batch or lot number where applicable for each product;

(*j*) manufacturing and expiring date where applicable for each product;

(*k*) mode of shipment; and

(*l*) signature and stamp of the supplier.

(4) Upon assessment of the application, the Authority shall require the applicant to pay the applicable importation fees as prescribed under the Pharmacy and Medicines Regulatory Authority (Fees and Forms) Regulations, 2026.

G.N. 27 of 2026

Application for import permit

5.—(1) A person who intends to import medicines, or allied substances shall submit to the Authority, an application for a permit in Form 2EI prescribed in the *Second Schedule*.

(2) The application made under subregulation (1) shall be accompanied by—

(*a*) certificate of analysis of all batches to be imported; and

(*b*) a copy of the final invoice, numbered and dated, duly filled and signed by the responsible officer of the business.

(3) Subject to subregulation (2)(*b*), the final invoice shall be issued in accordance with regulation 4(3).

(4) Upon assessment of the application, the Authority shall require the applicant to pay the applicable importation fees as prescribed under the Pharmacy and Medicines Regulatory Authority (Fees and Forms) Regulations, 2026.

G.N. 27 of 2026

Issuance of import permit

6.—(1) The Authority shall, within ten working days, consider the application for a permit to import medicines or allied substances and—

(*a*) upon being satisfied with its merits, grant the permit; or

(*b*) upon being dissatisfied with its merits, reject the application and give the applicant reasons for the rejection in writing.

(2) An import permit shall be in Form 3EI prescribed in the *Third Schedule*.

Validity of import permit

7. A permit issued under these regulations shall—

(*a*) be used for a single consignment;

(*b*) not be transferable to any other person and may be extended for such a period not exceeding three months, and

(*c*) of the minimum, contain name strength, dosage form, batch number, unit of issue, name of the manufacturer, and quantity of the medicines or allied substances.

Application for additional authorization for import of narcotic drugs, psychotropic substances or precursors

8. A person who intends to import any narcotic drug, psychotropic substance or precursor shall, in addition to an import permit, submit to the Authority an application for an additional authorization in Form 4EI prescribed in the *Fourth Schedule*.

Issuance of additional authorization for import of narcotic drugs, psychotropic substances or precursors

9.—(1) The Authority shall, within ten working days, consider the application for an additional authorization to import narcotic drugs, psychotropic substances or precursors and—

(*a*) upon being satisfied with its merits, grant the permit; or

(*b*) upon being dissatisfied with its merits, reject the application and give the applicant reasons for the rejection in writing.

(2) The additional authorization shall be in Form 5EI prescribed in the *Fifth Schedule*.

Revocation, cancellation or suspension of import permit

10.—(1) The Authority may revoke, cancel or suspend any permit issued under these Regulations, where it is satisfied that the importer or consignment contravenes any provision of the Act, these Regulations or any conditions of the permit.

(2) The Authority shall, prior to suspending, cancelling or revoking a permit, give an opportunity to the permit holder to show cause why the permit should not be suspended, cancelled or revoked, as the case may be.

(3) Pending the hearing under subregulation (2), the Authority may provisionally suspend the permit where it would be in the interest of justice so to do.

Change of batch numbers after issuance of an import permit for medicines and allied substances

11.—(1) Where a supplier changes the batch number of a registered medicine or allied substance, the applicant shall notify the Authority of such change and submit a certificate of analysis corresponding to the new batch number.

(2) A change of batch number in respect of an unregistered medicine or allied substance shall not be permitted under an existing authorisation, and the applicant shall submit a fresh application in accordance with regulation 4.

Register of permits

12.—(1) The Authority shall keep and maintain a register of permits in Form 6EI set out in the *Sixth Schedule*.

(2) The register shall be available for inspection by members of the public during normal working hours.

Conditions for importation of products for personal use

13.—(1) A person who intends to import medicines or allied substances for personal use shall submit an application to the Authority through a registered pharmacy.

(2) Subject to sub-regulation (1), an application for importation of medicines or allied substances for personal use shall be accompanied by a prescription from authorised prescriber.

(3) Unless the prescription under sub-regulation (2) states otherwise, any bonafide tourist or visitor who enters into, or person ordinarily resident who re-enters Malawi, may bring with him such quantity of any drugs as may be required during a period of six months for the medical treatment of himself, or any member, or partner travelling with him and such drugs shall be accompanied by a prescription from authorised prescriber and a letter giving reasons for such importation.

Importation of free medical samples

14.—(1) A person shall not sell, offer for sale or have in his possession for sale, free medical samples unless the person holds an import permit.

(2) Subject to other conditions set in these Regulations, an imported free medical sample shall—

(*a*) bear a label printed "free sample – not for sale" in bold letters; and

(*b*) be in a small pack that is adequate for one patient as opposed to a commercial pack.

(3) Any application for importation of free medical samples which do not meet the criteria stipulated under sub-regulation (2) shall be charged such fee as the Authority may prescribe.

Labelling of imported medicines and allied substances

15. An importer shall label all imported medicines and allied substances and make sure that the—

(*a*) information printed on labels is indelible, engraved or embossed on a primary and secondary container;

(*b*) immediate outer packaging of the medicines and allied substances is clearly labelled in English or Chichewa, or both;

(*c*) trade or brand name where appropriate is stated;

(*d*) international non-proprietary name is clearly stated;

(e) quantities of active ingredients in the given formulation are stated;

(*f*) dates of manufacture and expiry are indicated;

(*g*) batch or lot number are indicated;

(*h*) storage conditions are indicated;

(*i*) name and address of manufacturer are indicated;

(*j*) registration number of the product issued by the Authority in both outer and inner package of the product where applicable, is indicated;

(*k*) package insert literature is in English or Chichewa, or both; and

(*l*) specification of active pharmaceutical ingredient is given according to officially recognised pharmacopoeia.

Inspection of imported consignment at port of entry

16.—(1) A person shall not remove, or cause to be removed, any imported medicine or allied substance from a designated port of entry unless the medicine or allied substance has been inspected and authorised for release by an inspector.

(2) An importer shall, upon request by an inspector, produce such documents or information as the inspector may reasonably require for the purposes of verifying compliance with these Regulations.

(3) Where a consignment of medicines or allied substances is transferred by the Malawi Revenue Authority from a designated port of entry to another place for purposes of storage, customs clearance or any other lawful purpose, that place shall, for the purposes of inspection and release under these Regulations, be deemed to be a designated port of entry.

(4) The Malawi Revenue Authority shall not release any imported medicine or allied substance unless the importer produces a valid import permit issued by the Authority in accordance with these Regulations.

Sampling for quality control

17.—(1) An inspector may, at any designated port of entry, collect samples of imported medicines or allied substances for purposes of quality control testing without payment of any fee or compensation for the samples so collected.

(2) An inspector who collects samples under subregulation (1) shall complete and sign a Sample Collection Form 7EI prescribed in the *Seventh Schedule*.

Rejection, detention and disposal of consignments

18.—(1) Where an inspector has reasonable grounds to believe that a consignment of medicines or allied substances does not comply with the requirements of these Regulations or is otherwise unfit for its intended use, the inspector may detain the consignment and recommend to the Authority that the consignment be destroyed or returned to the country of origin.

(2) Before directing the destruction of a consignment under subregulation (1), the Authority shall consider whether the consignment may appropriately be returned to the country of origin.

(3) Where the Authority directs that a consignment be destroyed or returned to the country of origin under this regulation, the importer shall bear all costs associated with the destruction or return of the consignment.

(4) The Authority shall not make a final decision directing the destruction or return of a consignment under this regulation without first giving the importer an opportunity to be heard.

(5) The destruction of any consignment under this regulation shall be carried out in accordance with the Pharmacy and Medicines Regulatory Authority (Disposal of Unfit Products) Regulations in force at that time.

Part III

Offences and Penalties

Non-compliance with terms and conditions of import permit

19. A person who imports any medicine or allied substance otherwise than in accordance with the terms and conditions specified in the import permit commits an offence and shall, upon conviction, be liable to a fine of K4,000,000 and to imprisonment for four years

Import of medicines and allied substances not specified in import permit

20. A person who imports any medicine or allied substance different from that specified in the import permit commits an offence and shall, upon conviction, be liable to a fine of K4,000,000 and to imprisonment for four years

Import of medicines and allied substances in excess of quantity specified in import permit

21. A person who imports a quantity of medicine or allied substance in excess of the quantity authorized in the import permit commits an offence and shall, upon conviction, be liable to a fine of K3,000,000 and to imprisonment for three years

Import of narcotic drug, psychotropic substances and precursor without authorization

22. A person who imports any narcotic drug, psychotropic substance, precursor or other controlled substance without obtaining additional authorization commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years

Misrepresentation to obtain import permit

23. A person who knowingly makes or submits any false or misleading statement, declaration, invoice, prescription, certificate or other document for the purpose of obtaining an import permit commits an offence and shall, upon conviction, be liable to a fine of K3,000,000 and to imprisonment for three years.

Alteration, transfer or misuse of import permits

24. A person who alters, transfers, lends, misuses or permits another person to use an import permit otherwise than in accordance with the terms and conditions under which the permit was issued commits an offence and shall, upon conviction, be liable to a fine of K3,000,000 and to imprisonment for three years.

Prohibition of commercial use of medicines under an import permit for personal use

25. A person who imports medicines under an import permit issued for personal use where such medicines are intended for sale, supply, distribution or any other commercial purpose commits an offence and shall, upon conviction, be liable to a fine of K5,000,000 and to imprisonment for five years

Additional penalties

26.—(1) Upon conviction of any person of an offence under these Regulations, the court may in addition to any other penalty imposed, order—

(*a*) the forfeiture of any medicine, allied substance or other article connected with the commission of the offence;

(*b*) the destruction or other appropriate disposal of the medicine or allied substance, without compensation to the offender; or

(*c*) such other order or penalty as may be authorized under the Act.

Disciplinary action against pharmacists, pharmacist interns, pharmacist assistants, or pharmacy technicians

27. Where a pharmacist, pharmacist intern, pharmacist assistant, or a pharmacy technician—

(*a*) import or causes to be imported any medicine or allied substance without a valid import permit;

(*b*) knowingly import any substandard, falsified, unregistered or otherwise unauthorized medicine or allied substance;

(*c*) knowingly provides false or misleading information for the purpose of obtaining an import permit; or

(*d*) knowingly facilitates the unlawful importation of any medicine or allied substance,

such conduct shall, without prejudice to any criminal proceedings that may be instituted under the Act, constitute grounds for disciplinary proceedings in accordance with the Act.

FIRST SCHEDULE reg. 4(2)

FORM 1EI

APPLICATION FOR IMPORTATION OF UNREGISTERED MEDICINES OR ALLIED SUBSTANCES

Note

This form should be completed clearly and legibly, preferably in printed form. Failure to complete the form properly or to sign the declaration may result in delays in processing the application.

To: The Director General
Pharmacy and Medicines Regulatory Authority
P.O Box 30142
Capital City
Lilongwe

I/We …….....……of (postal address) .....undertaking the business of Wholesale pharmacy/Manufacturing, hereby apply for permit to import medicines and allied substances into Malawi through …… ……..... Port of entry.

Premises Registration Number ……

Name of Pharmacist Manager ……. Registration Number.....

Purpose of import permit: (*tick where applicable*)

☐ Importation of active pharmaceutical ingredient for production of pharmaceuticals for human use;

☐ Importation of active pharmaceutical ingredient for production of pharmaceuticals for veterinary medicines;

☐ Importation of Finished medicines and allied substances for human use;

☐ Importation of Finished medicines and allied substances for veterinary use;

☐ Importation of Pharmaceutical product for Personal use

☐ Importation of registered and or unregistered medicines and allied substances.

☐ Other……. (*specify*)

Note: *Declare whether the product is registered or unregistered.*

Particulars of products to be imported (If the space provided is insufficient, please add additional sheets)

No	*Name of Product (Brand)*	*Generic name and strength*	*Manufacturer & Country of Origin*	*Batch No*	*Unit Pack Size*	*Total Quantity (Units)*

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.

Date of application .....

Signature of Pharmacist Manager .....

Company Date Stamp .....

PMRA Date Stamp:

SECOND SCHEDULE (reg. 5(1))

FORM 2EI

APPLICATION FOR IMPORT PERMIT FOR MEDICINES OR ALLIED SUBSTANCES

PART A:

Name of registered importer ..... Postal address ..... Tel No .....

Exporting Country ..... Invoice No..... Date .....Time .....

Exporter/Sender ..... Postal address .....

Arrival expected by ship/air/motor vehicle, via ..... Port of entry

No	*Name of Product (Brand)*	*Generic name and strength*	*Manufacturer & Country of Origin*	*Batch No*	*PMRA Reg. No.*	*Unit Pack Size*	*Total Quantity (Units)*

Fees Paid (MK) Receipt No Date

....

PART B:

TO MRA and Importer

1. Permission is hereby granted to import the mentioned product(s).
2. However, the importer has to call Pharmacy and Medicines Regulatory Authority for an Inspector to come and examine the approved product(s) for fitness for the intended use before clearance and release across the border into Malawi or to the Malawi market.

....

Date *Director General*

PMRA Stamp

THIRD SCHEDULE (Reg. 6 (2))

FORM 3EI

Import Permit No.....

IMPORT PERMIT

PART A:

Wholesale License No/Clinical trial No. ..... Date .....

Exporter Name ..... Address .....Region .....

PERMIT TO IMPORT PHARMACEUTICALS FROM MALAWI

TO .....

BY .....

Reference is made to your application received on ..... attached with a proforma invoice number .....dated .....

Permission is hereby granted/declined to ....., under section (58) of the Pharmacy and Medicines Regulatory Authority Act, to import the following product(s) to.....

No	*Name of Product (Brand)*	*Generic name and strength*	*Manufacturer & Country of Origin*	*Batch No*	*PMRA Reg. No.*	*Unit Pack Size*	*Total Quantity (Units)*

No	*Name of Product (Brand)*	*Generic name and strength*	*Manufacturer & Country of Origin*	*Batch No*	*PMRA Reg. No.*	*Unit Pack Size*	*Total Quantity (Units)*

The import permit is issued on the following conditions:

1 That the importer shall comply with the applicable licensing requirements under the PMRA Act No. 9 of 2019.

2 That the importer shall maintain proper records on the import and supply of products.

3 That this import permit does not waive the product from satisfying all requirements for product labelling in Malawi, including labelling in the English language.

4 That PMRA may take samples for quality control analysis upon arrival of the consignment at its discretion.

This permit is valid from ..... to ..... Port of entry .....

....

Date *Director General*

PMRA Stamp

PART B:

To MRA and Importer

1. Permission is hereby granted to import the mentioned product(s).
2. However, the importer has to call the Pharmacy and Medicines Regulatory Authority for an Inspector to come and examine the approved product(s) for compliance with the permit in terms of products, quality and quantities before clearance and release across the border out of Malawi.

....

Date *Director General*

PMRA Stamp

Note: This permit is for single consignment only and shall be valid for ..... days only from date of approval.

FOURTH SCHEDULE (reg 8)

FORM 4EI

APPLICATION FOR ADDITIONAL AUTHORIZATION FOR IMPORT OF NARCOTIC DRUGS, PSYCHOTIC SUBSTANCES OR PRECURSORS

Product details

1. Proprietary (Trade) Name	2. Non-proprietary name (INN)		3. PMRA Product Registration No.
4. Strength and dosage form	5. Quantity required including pack size	6. Value in US$	7. Reason for importation

Local Applicant and shipment details

1. Name of Applicant	2. Qualification(s)	3. Registration No.	4. Authorised Signature and Official stamp
5. Address of Applicant			6. Business category of applicant; Wholesaler/ Retailer/ Hospital/ Other (specify)
7. Tel No.	8. Fax No.		9. E-mail address
10. Mode of shipping of consignment and port of entry in Malawi			11.Expected date of arrival of consignment

Supplier details

1. Name of Supplier and Postal Address		2. Physical Address
3. City/town	4. Country	5. Contact Person
6. Tel No.	7. Fax No.	8. E-mail address

For Official use only

Payment Received: MK .....

PMRA Receipt Number . .....

Approved/Rejected to issue permit ..... Date .....

Director General, PMRA

FIFTH SCHEDULE (reg. 9 (2))

FORM 5EI

NARCOTIC LICENCE

NARCOTIC PERMIT (ADDITIONAL AUTHORIZATION)

International Opium Convention

(*The Hague 1912, Geneva 1925, Limitation Convention 1931*)

Narcotic Import License No: 00XXX

LICENCE TO IMPORT DANGEROUS DRUGS

I hereby certify that the Government of Malawi being charged with the administration of the law relating to the Dangerous Drugs to which International Opium Convention apply has approved the importation by—

(1)	Name of importer:	.....
(2)	Address of:	.....
(3)	Precise description (*generic name, strength and quantity of drug to be imported*)	(*a*) (Quantity): ..... (*b*) (Description): ..... (*c*) (Strength) .....
(4)	Name of supplier in exporting country	.....
(5)	Address of supplier: in exporting country from which the drug(s) is/are to be obtained	.....
(6)	State special conditions to be observed, (*e.g. not to be imported through the post*)	.....
(7)	State Customs Office through which the goods will be imported	.....
(8)	State route to be followed by the goods (*Air, Road, Sea*)	.....
(9)	Period within which the Import is to be effected and is satisfied that the	.....

consignment proposed to
be imported is required:

(1) *for legitimate purposes*

(2) *solely for medical or scientific purposes*

Signed on behalf of the Government of Malawi

Name of issuing Officer: ..... Signature:.....

Official Rank: ..... Date of issue: .....

SIXTH SCHEDULE (Reg. 12) (1))

FORM 6EI

REGISTER OF IMPORT PERMITS

Import Permit Number	*Date of issue*	*Name of the Importer*	*Name of the Exporter*	*Invoice number*

SEVENTH SCHEDULE (Reg. 17 (2))

FORM 7EI

SAMPLE COLLECTION FORM

1. Sample name and code (*if applicable*: .....
.....(*Region/product/sequence number/sampling date*)
2. Name of Port/Premises where sample was taken: .....
3. Address .....
Telephone No .....
Email address .....
4. Product name of the sample: .....
5. Name of active pharmaceutical ingredient(s) (INN) with strength: .....

6. Dosage form (tablet, oral powder, etc): .....
7. Package size & type: .....
8. Batch/lot number: .....
9. Date of manufacture: .....
10. Expiry date .....
11. Name and physical address of the manufacturer .....
12. Number of units collected .....
13. Is the product registered in Malawi? Yes/No. If Yes, indicate the registration number: .....
14. Comment on storage condition of product at the premises: .....
    .....
15. Name and signature of the Customs Officer/Representative of the premise where sample was collected:
    Name ..... Signature ..... Date .....
16. Name of the Sampling officer

S.No	*Name*	*Organization*	*Signature*	*Date*

Note: *Samples collected must remain in their original containers*

Collected by ..... Date .....

Signature .....

FOR OFFICIAL USE ONLY

Sample delivered and received at the Testing Laboratory: Yes/ No

Date delivered .....

Test Fess Paid: Yes / No ..... MK ..... Receipt No .....

Sample Test Result: Pass / Fail .....

Donation Approved for use: Yes / No .....

Date ..... Director General .....

Made this 11th day of November, 2026.

M. BALOYI
Minister of Health and Sanitation

(FILE NO:PMRA/MOFI/05/09/2024)