GOVERNMENT NOTICE NO. 95

PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT

(NO. 9 OF 2019)

PHARMACY AND MEDICINES REGULATORY (EXPORT) REGULATIONS, 2026

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IN EXERCISE of powers conferred by section 129 as read together with section 59 (3) 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 (Export) Regulations, 2026.

Interpretation

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

"controlled drugs" means any narcotic drugs, psychotropic substances or precursors;

"export permit" means a provisional permit issued, per consignment, by the Authority to an Exporter authorizing him to export medicines and allied substances from Malawi;

"exporter" means a person or institution authorized under these Regulations to export medicines and allied substances from Malawi; and

"port of export" means an existing point for exporting medicines and allied substances.

PART II—EXPORTATION OF MEDICINES AND ALLIED SUBSTANCES

Requirements for exporter of medicines and allied substances

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

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

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

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

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

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

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

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

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

(3) A person shall not export an active pharmaceutical ingredient unless the person is a licensed pharmaceutical manufacturer.

Application for export permits

4.—(1) A person who intends to export medicines, or allied substances shall apply to the Authority for a permit in Form 1EI prescribed in the *First Schedule*.

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

(*a*) an import permit issued by the importing country;

(*b*) where the product is not manufactured locally, an import permit issued by the Authority as evidence that the product was imported legally; and

(*c*) proof of payment of the fee prescribed in the Pharmacy, Medicines Regulatory Authority (Fees and Forms) Regulations. No. 27 of 2026

Application for export permits for individual use

5.—(1) A person who intends to export medicines for his or her personal use shall apply to the Authority for an export permit in Form 1EI prescribed in the *First Schedule.*

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

(*a*) a valid prescription issued by a duly qualified and registered health practitioner, where the medicine is a prescription-only medicine;

(*b*) documentary evidence demonstrating that the medicine was purchased or otherwise lawfully obtained from a pharmacy registered by the Authority; and

(*c*) such other information or documentation as the Authority may reasonably require for the purpose of determining the application.

(3) The quantity of medicine applied for under subregulation (1) shall—

(*a*) be consistent with the quantity prescribed in the prescription submitted under subregulation (2)(*a*); and

(*b*) be reasonably required for the personal use of the applicant for the period specified in the prescription.

Issuance of export permits

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

(*a*) is satisfied with its merits of the application, issue the permit; or

(*b*) is not satisfied with its merits of the application, reject the application and give the applicant reasons for the rejection in writing.

(2) An export permit shall be in the Form 2EI prescribed in the *Second Schedule*.

Validity of export permits

7. An export 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*) at a minimum, contain the name and quantity of the medicines or allied substances.

Revocation, cancellation or suspension of export permits

8.—(1) The Authority may revoke, cancel or suspend any permit issued under these Regulations, where it is satisfied that the exporter 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) The Authority may, pending the hearing under subregulation (2), provisionally suspend the permit where it would be in the interest of justice so to do.

Register of permits

9.—(1) The Authority shall keep and maintain a register of permits in Form 3EI set out in the *Third Schedule*.

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

Part III—Offences and Penalties

Non-compliance with terms and conditions of export permit

10. A person who exports any medicine or allied substance otherwise than in accordance with the terms and conditions specified in the export permit, commits an offence and shall, upon conviction, be liable to a fine of K3,000,000 and to imprisonment for three years.

Export of medicines and allied substances not specified in export permit

11. A person who exports any medicine or allied substance different from that specified in the export permit, commits an offence and shall, upon conviction, be liable to a fine of K2,000,000 and to imprisonment for two years.

Export of medicines and allied substances in excess of quantity specified in export permit

12. A person who exports a quantity of medicine or allied substance in excess of the quantity authorized in the export permit, commits an offence and shall, upon conviction, be liable to a fine of K2,000,000 and to imprisonment for two years.

Misrepresentation to obtain export permit

13. 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 export 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 export permits

14. A person who alters, transfers, lends, misuses or permits another person to use an export 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.

Additional penalties

15.—(1) The court may, where a person is convicted of an offence under these Regulations, 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

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

(*a*) exports or causes to be exported any medicine or allied substance without a valid export permit;

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

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

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

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

FIRST SCHEDULE (reg. 4 (1))

FORM 1EI

APPLICATION FOR EXPORTATION OF UNREGISTERED MEDICINES OR ALLIED SUBSTANCES

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 (address) .....undertaking the business of pharmaceutical wholesale, hereby apply for a permit to export medicines and allied substances from Malawi through …… ..... Port of entry.

Premises Registration Number ……

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

(NB: *Where medicines are being exported by an individual, only the section requiring the exporter's name and address shall be completed.*)

Name of Consignee .....

Physical address/Location of business .....

Country name .....

Purpose of export permit: (tick where applicable):

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

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

☐ Exportation of a specified product for Clinical Trial (one product per application)

☐ Exportation of raw materials and/or packaging materials for production of pharmaceuticals for human use;

☐ Other (*specify*) …….

Details of the Consignment:

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

NB: Where medicines are intended for export by an individual, a PMRA registration number shall not be required. However, the products intended for importation shall be submitted to the Authority for verification of the relevant information.

Declaration:

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

Date of application .....

Signature of the Responsible Pharmacist .....

Company Date Stamp .....

For official use only:

Fees (MK) ..... Receipt No ..... Date .....

Received by: ..... Signature .....

PMRA Date Stamp:

SECOND SCHEDULE (reg. 5(2))

FORM 2EI

EXPORT PERMIT FOR MEDICINES AND ALLIED SUBSTANCES

PART A:

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

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

PERMIT TO EXPORT PHARMACEUTICALS FROM MALAWI

TO ……...…….

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

Permission is hereby granted / declined to ....., under section (59) of the Pharmacy and Medicines Regulatory Authority Act to export the following product(s):

Details of the consignment:

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)*

Declaration: This export permit is issued solely for the purpose of facilitating clearance of the products at the port of export. The exporter shall be responsible for ensuring compliance with all applicable regulatory requirements of the importing country. The Pharmacy and Medicines Regulatory Authority shall not be liable for any non-compliance, loss, damage, claim, or other consequence arising in the importing country in connection with the products exported under this permit.

....

Date *Director General*

PMRA Stamp

PART B:

To MRA and Exporter

1. Permission is hereby granted to export the mentioned product(s).
2. However, the exporter 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.

THIRD SCHEDULE (Reg. 9(1)

THE REGISTER OF EXPORT PERMITS

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

Made this 11th day of November , 2026.

M. BALOYI
Minister of Health and Sanitation

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