LEGAL NOTICE NO. 97

THE PHARMACY AND POISONS ACT

(*Cap*. 244)

THE PHARMACY AND POISONS (TRANSPORTATION OF PHARMACEUTICALS) RULES, 2022

ARRANGEMENT OF RULES

Rule

THE PHARMACY AND POISONS ACT

(*Cap*. 244)

IN EXERCISE of the powers conferred by section 44 of the Pharmacy and Poisons Act, the Cabinet Secretary for Health, in consultation with the Pharmacy and Poisons Board, makes the following Rules—

THE PHARMACY AND POISONS (TRANSPORTATION OF PHARMACEUTICALS) RULES, 2022

PART I—PRELIMINARY

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Transportation of Pharmaceuticals) Rules, 2022.

Interpretation.

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

"cold chain" means any material, equipment, process or procedure used to maintain a product within the required temperature range of 2 °C to 8 °C or according to the manufacturer's recommended storage conditions from the time of manufacture until the product is administered to an individual;

"consignment" means the quantity of pharmaceuticals supplied at one time in response to a particular request or order and may comprise one or more packages or containers which may include pharmaceuticals belonging to more than one batch;

"consignor" means a person engaged in the activity of distributing pharmaceuticals;

"consignee" means a person to whom goods or documents are officially sent or delivered ;

"container" means the material employed in the packaging of a pharmaceutical and may include a primary or secondary transportation container;

"importation" means the act of bringing or causing any pharmaceuticals to be brought into Kenya;

"primary container" means a container that is intended to be in direct contact with a product;

"product recall" means the removal of specific batches of a pharmaceutical from the market due to deficiency in quality, safety or efficacy of a pharmaceutical;

"secondary container" means a container that is not intended to be in direct contact with a product;

"storage" means the storing of pharmaceuticals up to the point of use;

"transit" means the period during which pharmaceuticals are in the process of being carried, conveyed or transported across, over or through a passage or route to reach the destination; and

"vehicle" means a carrier which can be used to convey pharmaceuticals from one point to another and includes a motorcycle, bicycle, truck, van, bus, minibus, car, trailer, aircraft, railway carriage, boat or other means which are used to convey pharmaceuticals.

Objectives of the Rules.

3. The objectives of these Rules are to—

(a) provide for the licensing transporters of pharmaceuticals;

(b) provide for the enforcement transportation requirements;

(c) ensure the security of pharmaceuticals while on transit;

(d) ensure that any pharmaceuticals within the possession of transporters are accounted for; and

(e) ensure that any transported pharmaceuticals conform to the prescribed standards of quality, safety and efficacy.

Application.

4. These Rules shall apply to any person who is authorized to store, distribute or transport pharmaceuticals.

PART II—REQUIREMENTS FOR TRANSPORTATION OF PHARMACEUTICALS

Transportation licence.

5. (1) A person who intends to engage in the business of transporting pharmaceuticals shall make an application for a licence to the Board in Form 1 set out in the Schedule.

(2) An application under subrule (1) shall be accompanied by the following documents—

(a) a certificate of incorporation for a company, a registration certificate for a business name or partnership deed for a partnership;

(b) a certificate of registration of a registered pharmacist or an enrolment certificate of an enrolled pharmaceutical technologist appointed by the applicant;

(c) registration and inspection documents for any vehicles or vessel to be used in transporting pharmaceuticals issued by the relevant regulatory agencies;

(d) a licence for every operator of a vehicle;

(e) inspection reports on the suitability of any vehicle for transportation of pharmaceuticals from a competent authority;

(f) a declaration on the type of pharmaceuticals that the applicant intends to transport;

(g) for any vehicle that is to be used in the transportation of cold-chain products, a copy of a job card showing the installation and validation of the cold-chain control, monitoring and recording system with in-built alarm and alert capabilities from a duly registered and authorized firm; and

(h) any other information as shall be required by the Board.

(3) The Board shall review the application made under paragraph (1) and may approve or reject the application.

(4) Where the Board approves the application, the Board shall issue a licence in the Form 2 set out in the Schedule.

(5) Where the Board rejects the application, the Board shall, within fifteen days from the date of receipt of the application, communicate to the applicant the decision specifying reasons for the rejection, in writing.

(6) A person who is aggrieved by the decision of the Board may appeal to the High Court.

Enforcement.

6. (1) A licence issued under rule 5 may be revoked, suspended or modified for any of the reasons specified in subrule (3).

(2) The Board may prohibit the possession of a pharmaceutical product for any of the reasons specified in subrule (3).

(3) A person is liable to a decision of the Board under paragraph (1) or (2) if the person—

(a) contravenes these Rules; or

(b) an agent of the person provides misleading information.

(4) A person who is aggrieved by the decision of the Board under subrule (1) or (2) may appeal to the High Court.

Verification.

7. (1) A consignor shall, before commencing transportation, verify—

(a) the type of the pharmaceuticals that are to be transported and identify the appropriate protection arrangements for the consignment; and

(b) that the consignee is authorized to possess the pharmaceuticals.

(2) A person shall not transport any radioactive material without authorization from the Board.

(3) The Board may, before authorizing a person to transport radioactive material, consult the Nuclear Regulatory Authority and any relevant body established by any written law to regulate the transportation of radioactive materials.

(4) A person shall not use a motorcycle to transport narcotic, psychotropic substances or precursor chemical substances in accordance with the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances 1971, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988.

(5) A person who contravenes subrules (1), (2) or (4) commits an offence and shall, on conviction, be liable to the penalty prescribed in section 51 of the Act.

Security during transportation.

8. A person who is engaged in the transportation of pharmaceuticals shall—

(a) ensure that each vehicle is equipped with lockable doors or where possible an intruder alarm;

(b) document and track all deliveries; and

(c) keep signed dispatch and arrival records.

PART III—CATEGORIES OF TRANSPORT

Obligations of air transporters.

9. A person who is engaged in the transportation of pharmaceuticals by air shall ensure that—

(a) the pharmaceuticals meet the handling requirements stipulated by the manufacturer;

(b) that a time and temperature sensitive label is affixed on any shipment booked as time and temperature sensitive cargo;

(c) that an acceptance checklist for any time and temperature sensitive shipment is executed; and

(d) that an authorized officer of the Board is notified on the arrival of the shipment at the port of entry for pre-clearance inspection.

Obligations of sea transporters.

10. (1) A person who is engaged in the transportation of pharmaceuticals by sea shall ensure that—

(a) the pharmaceuticals are packaged in a refrigerated container for transporting temperature sensitive cargo in accordance with the storage specifications of the manufacturer;

(b) the importation of pharmaceuticals shall be through a *Gazetted* ports of entry that are equipped to handle the products;

(c) upon arrival at the port of entry, the pharmaceuticals are removed from the transporting vessel as soon as possible and moved to a safe and suitable temperature-controlled storage location to minimize the risk of temperature related damage and theft;

(d) he receives and forwards records of storage conditions during transportation to the authorized officer of the Board at the port of entry to confirm that storage is compliant while on transit;

(e) any excursion is reported to the owner of the consignment and the authorized officer of the Board at the port of entry so that it can be adequately addressed; and

(f) an authorized officer of the Board is notified on the arrival of the shipment at the port of entry for pre-clearance inspection.

(2) The conditions under subrule (1) shall also apply to the exportation of pharmaceuticals.

(3) A consignor shall ensure that a shipping container—

(a) protects the personnel and the general public from any hazard arising from spillage or leakage;

(b) protects the product being transported against mechanical damage and the temperature changes encountered during transit;

(c) is closed in a manner that allows the recipient of the consignment to establish that the product has not been tampered with during transportation; and

(d) is insulated.

(4) A consignor shall ensure that chemical or electric freeze indicators, electronic loggers or any other suitable indicators are used to monitor temperature or humidity exposure during transportation.

Obligations of road transporters.

11. A person who is engaged in transportation of pharmaceuticals by road shall ensure—

(a) that any vehicle or equipment used to distribute pharmaceuticals is suitable for its purpose and is appropriately equipped;

(b) that the design and use of any vehicle aims to minimize the risk of errors on the product being distributed;

(c) that tracking devices and engine kill buttons are installed on every vehicle; and

(d) the use of dedicated vehicles and equipment.

PART IV—SPECIFICATIONS

Loading and receiving bays.

12. (1) A person who is licensed to transport pharmaceuticals under these Rules shall ensure that—

(a) every loading, receiving or dispatch bay has sufficient facilities and space allowance to ensure pharmaceuticals are protected from adverse environmental conditions;

(b) any area where pharmaceuticals are temporarily held during arrival or dispatch is—

(i) maintained within the temperature and humidity range specified for the goods being handled;

(ii) protected from direct sunlight, dust or rain; and

(iii) adequately ventilated and lit;

(c) temperature and humidity are monitored at all times and documented in temperature logs or humidity logs which shall be maintained and readily available;

(d) any equipment, appliance or gadget used in temperature control is connected to uninterruptible power supply system and power back up; and

(e) temperature control equipment is calibrated as recommended by the manufacturer and the records are maintained.

Transport and delivery.

13. An authorized person shall ensure that any vessel used for transportation of pharmaceutical products is—

(a) equipped with calibrated temperature and humidity monitoring devices with sensors located at points representing temperature extremes;

(b) equipped with alarms to alert the operator in the event of temperature or humidity excursions or refrigeration unit failure; and

(c) fitted with doors with security seals or security locks that protect against unauthorized access during transit.

Monitoring of storage conditions during transit.

14. A person who is engaged in the transportation of pharmaceuticals shall ensure any vessel used in transportation is fitted with—

(a) temperature control systems that are able to continuously maintain air temperature within the set points and the accuracy shall be within 0.5 °C; and

(b) humidity control systems with an accuracy of + or -5% relative humidity.

Temperature controlled vehicles.

15. A consignor shall ensure that a temperature-controlled vessel demonstrates—

(a) that the air temperature and humidity is uniformly distributed in the temperature controlled compartment of the vessel by installing temperature probes; and

(b) the time taken for temperatures to exceed the designated maximum in the event that the temperature controlling unit fails.

Calibration of vessels.

16. (1) Any vessel used for transportation of pharmaceuticals shall undergo routine inspection.

(2) Any vessel used for transportation of temperature sensitive pharmaceuticals shall undergo calibration of devices for temperature and humidity control in accordance with recommendations of the manufacturer or at least once every year by the Kenya Bureau of Standards or any other certified standards accreditation body to ensure compliance.

Insulated containers.

17. (1) A consignor shall ensure that—

(a) for short terms periods of transportation of pharmaceuticals, insulated containers with icepacks are used; and

(b) for long periods of transportation of pharmaceuticals, insulated containers of up to ninety six hours are used.

(2) The sender shall ensure that the packaging system is capable of maintaining the pharmaceuticals within the temperature range.

(3) A consignee shall ensure that non-conforming pharmaceuticals are quarantined and shall, as soon as possible, report to the Board.

Contingency planning.

18. A consignor shall put in place contingency plans for the safe storage of pharmaceuticals in cases of extended power outages, equipment failure or vehicle breakdown in transit.

Record keeping.

19. (1) A transporter shall maintain records in paper and electronic formats.

(2) The paper records shall be—

(a) stored and maintained so that they are easily accessible;

(b) labeled, dated and filed for easy identification;

(c) protected against deterioration and loss due to fire, flood or other hazards;

(d) kept secure and protected against unauthorized access; and

(e) signed and dated by the authorized persons and not changed without due authorization;

(3) Electronic or computer records shall be—

(a) logically filed for easy identification and retrieval;

(b) kept secure and protected against unauthorized access;

(c) where feasible, manually signed, dated and scanned; and

(d) regularly backed-up and archived.

(4) The records referred to in paragraph (1) shall be kept for a period of at least two years and made available for inspection by authorized officers of the Board.

Standard operating procedures.

20. Every transporter, authorized persons, consignors and consignees shall comply with good distribution, transportation and storage practices requirements issued by the Board.

Compliance.

21. A person who intends to store, distribute or transport pharmaceuticals shall, within six months from the date of publication of these Rules, comply with the requirements under these Rules.

Offences and penalties.

22. A person who contravenes any of the provisions of these Rules commits an offence and shall be liable to the penalty prescribed under section 51 of the Act.

SCHEDULE

Form 1 r. 5(1)

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

APPLICATION FOR LICENSE TO TRANSPORT PHARMACEUTICALS FOR DISTRIBUTION

I /We, ...of .....here by apply for a license to transport pharmaceuticals

Part 1. Details of the applicant:

1.1 (a) Name of applicant: .....

(b) Designation: ..... Registration/Enrolment no.....

(c) National Identity Card/Passport No.....

(d) Mailing address: .....

(e) E-mail address .....

(f) Telephone No. .....

Part 2. Details of business

2.1 (a) Transportation of pharmaceuticals ☐ ☐

Where Part 2(a) is requested, attach copy of Premises Registration Certificate and Wholesale Dealer's license

Part 3. Type(s) of pharmaceuticals intended to be transported.

(a) Biological Products

(b) Vaccines

(c) Medical devices

(d) Finished Pharmaceutical products

(e) Active Pharmaceutical Ingredients

Part 4. Details of vehicle(s) /vessel(s)to be used in transport

Type of Vehicle	*Car*	*Van*	*Freezer truck*	*Others*
Vehicle Registration number				

(Add more lines if necessary)

Declaration

I, the undersigned, certify that all information in this application for license to transport pharmaceuticals for distribution is true and correct.

I understand that I have the responsibility to inform the Authority with immediate effect of any change to the information provided in this application.

Signature: .....

Applicant: .....

Name: .....

Designation: .....

Date: .....

Form 2 r.5(4)

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

LICENSE TO TRANSPORT PHARMACEUTICALS

Messrs.....

Address.....is registered to carry on the business of transportation of pharmaceuticals in the listed vessels and approved warehouse(s) as per the type(s) indicated.

i. Type(s) of pharmaceuticals transported.....

ii. Source and destination.....

iii. Registration number of the vessel.....

iv. Name and ID. No of the operator.....

Note: a) This registration expires on 31st December.....

b) No change of the transport vessel without the authority of the Board.

c) Any new vessel must be inspected by the Board before certification.

d) This registration shall become void upon expiration of 30 days from any change of the nature of the business.

Chief Executive Officer.....

Signature.....

Date.....

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.