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—PRELIMINARIES

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 all materials, equipment, processes and procedures used to maintain all products within the required temperature range of 2 ℃ to 8 ℃ (or as per the manufacturer's recommended storage conditions) from the time of manufacture until the products are administered to individuals;

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

"consignor" means a person or entity engaged in the activity of distribution of pharmaceuticals or services;

"Consignee" means a person or company to whom goods or documents are officially sent or delivered to.

"container" means the material employed in the packaging of a pharmaceutical. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product. Secondary containers are not intended to be in direct contact with the product;

"importation" means the act of bringing or causing any goods to be brought into a customs territory;

"product recall" means the removal of specific batches of a pharmaceutical from the market for reasons relating to deficiencies in quality, safety or efficacy;

"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;

"vehicles" means motorcycles, bicycle, trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages, boats and other means which are used to convey pharmaceuticals.

Objective of the Rules.

3. These Rules specify the basic requirements for—

(a) Licensing transporters of pharmaceuticals;

(b) Enforcement of transportation requirements;

(c) the security of pharmaceuticals while on transit;

(d) accounting for the pharmaceuticals within the possession of transporters; and

(e) ensuring that all pharmaceuticals transported conform to prescribed standards of quality, safety and efficacy.

Application.

4. (1) These Rules apply to all persons authorized to use, store, distribute and transport pharmaceuticals.

(2) These Rules do not apply to pharmaceuticals within military or defense programs or any other national security organ, agency or service.

PART II—REQUIREMENTS FOR TRANSPORTATION OF PHARMACEUTICALS

Licence.

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

(2) An application under sub-rule (1) shall be accompanied by the following documents—

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

(b) a certificate of registration of a registered pharmacist or an enrolment certificate of an enrolled pharmaceutical technologist appointed by the person who shall be approved by the Board for enterprises applying for transportation and warehousing of medicinal products;

(c) registration and inspection documents for all vehicles or vessels to be used for transporting pharmaceuticals from approved agencies;

(d) licences for operators of the vehicles or vessels;

(e) inspection reports from the Board on the suitability of the premises used by the applicant;

(f) inspection reports on suitability of the vessels for transportation of pharmaceuticals from a competent authority;

(g) declaration on what type of pharmaceuticals the applicant will engage in transporting;

(h) for vessels to be used in transport 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, alert capabilities from a duly registered and authorized firm; and

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

(3) The Board shall review the application under sub-rule (1) and may approve or reject the application.

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

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

(6) A person aggrieved by the decision of the Board may appeal to court.

Enforcement.

6. (1) A licence may be revoked, suspended or modified for any of the reasons specified in sub-rule (3).

(2) The Board may prohibit the possession of pharmaceutical products for any of the reasons specified in sub-rule (3).

(3) A person is liable for a decision of the Board under sub-rule (1) or (2) where the person—

(a) does not comply with these Rules; or

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

(4) Any person may appeal to court against a decision of the Board under sub-rule (1) or (2).

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 radioactive material without authorization from the Board.

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

(4) A person shall not use a motorcycle to transport narcotic, psychotropic substances and precursor chemical substances in accordance with either 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 transports radioactive material without written authorization from the Board commits an offence and shall, on conviction, be liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding five years, or to both.

Security during transportation.

8. A person engaged in transportation of health products shall ensure that—

(a) vessels are equipped with lockable doors or where possible an intruder alarm;

(b) security cleared delivery drivers are employed;

(c) all deliveries are documented and tracked; and

(d) signed dispatch and arrival records are kept.

PART III—CATEGORIES OF TRANSPORT

Air transport.

9. A person engaged in air transportation of pharmaceuticals shall ensure—

(a) all health and health care products handling meets the IATA requirements for aircrafts;

(b) that a time and temperature sensitive label is affixed on all shipments booked as time and temperature sensitive cargo and the external transportation temperature range of the shipment;

(c) that an acceptance checklist for time and temperature sensitive shipments are executed; and

(d) that the Pharmacy and Poisons Board authorized officer be notified on the arrival of the shipment at the port of entry for pre-clearance inspection.

Sea transport.

10. (1) A person engaged in sea transportation of pharmaceuticals shall ensure—

(a) that the pharmaceuticals are packaged in a refrigerated container for transporting temperature sensitive cargo in accordance with the manufacturer's storage specifications;
(b) that import of pharmaceuticals must be through a *Gazetted* ports of entry that are equipped to handle the products;
(c) that upon arrival at the port of entry, the pharmaceuticals shall be 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) they receive and forward records of storage conditions during transportation to the authorized officer at the port of entry to ensure storage is compliant while on transit;
(e) any excursions are reported to the owner of the consignment and PPB authorized officer at the ports of Entry so that it can be adequately addressed; and
(f) that the Pharmacy and Poisons Board authorized officer be notified on the arrival of the shipment at the port of entry for pre-clearance inspection.

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

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

(a) protect the personnel and the general public from hazards arising from spillage or leakage;

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

(c) are 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) are insulated.

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

Road transport.

11. A road transporter shall ensure—

(a) vehicles and equipment used to distribute pharmaceuticals are suitable for their purpose and appropriately equipped;

(b) the design and use of vehicles aims to minimize the risk of errors on products being distributed;

(c) tracking devices and engine kill buttons are installed on vehicles; and

(d) use of dedicated vehicles and equipment.

PART IV—SPECIFICATIONS

Loading and receiving bays.

12. (1) An authorized person shall ensure that—

(a) Loading, receiving and dispatch bays shall have sufficient facilities and space allowance to ensure pharmaceuticals are protected from adverse environmental conditions;

(b) areas where pharmaceuticals are temporarily held during arrival or dispatch are—

(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) equipment, appliances or gadgets used in temperature control are connected to uninterruptible power supply system and power back up; and

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

Transport and delivery.

13. An authorized person shall ensure that vessels used for transportation of pharmaceutical products are—

(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, humidity excursions or refrigeration unit failure; and

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

Monitoring of storage conditions during transit.

14. A person engaged in the transportation of pharmaceuticals shall ensure vessels used in transportation are 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 ℃; and

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

Temperature controlled vehicles.

15. A consignor shall ensure that temperature-controlled vessels demonstrate—

(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.

16. All vessels used for transportation of pharmaceuticals shall undergo routine inspection and calibration of devices for temperature and humidity control as per the manufacturer's recommendations or at least once every year by the Kenya Bureau of Standards or any other certified standards accredidation body to ensure compliance.

Insulated containers.

17. (1) A consignor shall ensure that containers used in transportation of pharmaceuticals—

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

(b) for long periods of transportation, insulated containers of up to 96 hours shall be used.

(2) It shall be the responsibility of the sender to ensure that the packaging system is capable of maintaining the pharmaceuticals within the temperature range.

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

Emergencies and contingency planning.

18. A consignor shall ensure that 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.

(a) paper records shall be—

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

(ii) labelled, dated and filled for easy identification;

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

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

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

(b) electronic or computer records shall be—

(i) logically filed for easy identification and retrieval;

(ii) kept secure and protected against unauthorized access;

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

(iv) regularly backed-up and archived.

(2) Records reffered under sub-rule 1 shall be made available for inspection by authorized officers of the Board for a period of at least two (2) years.

Standard operating procedures.

20. (1)A person engaging in transporting pharmaceuticals shall develop, domesticate and maintain standard operating procedures on correct transport of pharmaceuticals.

(2) Every transporter, authorized persons, consignors and consignees shall comply with good distribution, transporation and storage practices requirements issued by the Board.

Compliance.

21. All persons authorized to use, store, distribute and transport pharmaceuticals shall, within six months from the date of publication of these Rules, comply with the requirements under these Rules.

Offences.

22. A person who contravenes any of the provisions of these Rules commits an offence and is liable on conviction to a fine not exceeding one million shillings or to imprisonment for a term not exceeding one year, or both.

SCHEDULE 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: ..... Reg/Enrol 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 and warehousing of pharmaceutical products ☐

(c) 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: .....

Schedule 2 **R.5(4)**

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

LICENSE TO TRANSPORT PHARMACEUTICALS AND HEALTH PRODUCTS

Messrs.....

Address.....is registered to carry on the business of transportation of pharmaceuticals and 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 PPB before certification

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

Chief Executive Officer……

Signature……

Date……

Made on the ……..., 2022.

MUTAHI KAGWE
Cabinet Secretary for Health.