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THE PHARMACY AND POISONS ACT

(*Cap.* 244)

THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES, 2019

ARRANGEMENT OF RULES

Rule

PART I—PRELIMINARY

1— Citation.

2— Application.

3— Interpretation.

PART II- CERTIFICATE OF PARALLEL IMPORTATION AND PARALLEL IMPORT LICENCE

4— Qualification to parallel import medicinal substances.

5— Application for a certificate of parallel importation.

6— Issuance for a certificate of parallel importation.

7— Certificate of parallel importation not transferable.

8—Validity of certificate of parallel importation.

9—Rejection of an application for a certificate of parallel importation.

10—Application for renewal of certificate of parallel importation.

11—Application for parallel import licence.

12—Additional requirements by the Board.

13—Board inquiries in country of origin

14—Issuance of licence.

15—Licence not transferable.

16—Validity of licence.

17—Rejection of an application for a parallel import licence.

18—General conditions of parallel import licence.

19—Application for renewal of a parallel import licence.

20—Revocation, variation and suspension of parallel import licence.

21—Suspension of use, sale, supply or offer for sale or supply of medicinal substances.

22—Recall of a medicinal substance from the market.

PART III—INVENTORY OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

23— Inventory of parallel imported medicinal substances.

24— Record-keeping obligations.

PART IV—PHARMACOVIGILANCE

25— Pharmacovigilance issues.

26— Additional obligations.

PART V—PRICING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

27—Principles of pricing of parallel imported medicinal substances.

28— Pricing guidelines.

PART VI—PACKAGING AND LABELLING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

29— Labelling and packaging guidelines.

PART VII—INSPECTIONS

30— Places authorised officers may enter.

31— Powers of authorised officers.

32— Use of records.

33— Entry of dwelling place.

34— Magistrate courts to issue warrant.

35— Use of force.

36— Certificate of analysis.

37— Assistance of an authorised officer.

38— Obstruction.

39— Seizure.

40— Order for restoration.

41— Rejection of an application for order of restoration.

42— Appeals

PART VIII—TRACING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

43— Establishment of a tracing system.

44— Data matrix of medicinal substances.

45— Functions of the tracing system.

46— Duties of a licensee.

47— Batch recalls.

PART IX—THE PARALLEL IMPORTATION APPEALS COMMITTEE

48— The Appeals Committee.

49— Procedure on Appeals.

PART X—MISCELLANEOUS PROVISIONS

50—Transition.

51—Offences in connection with application of parallel import licence.

52—Provision of false or misleading information.

53—Failure to comply with urgent safety restrictions.

54—The offence of use, sale, supply, e.t.c of a suspended medicinal substance.

55—General offence of breach of provision of these rules.

FIRST SCHEDULE–APPLICATION FOR A CERTIFICATE OF PARALLEL IMPORTATION OR RENEWAL OF CERTIFICATE OF PARALLEL IMPORTATION

SECOND SCHEDULE—FEES

THIRD SCHEDULE—CONDUCT OF PROCEEDINGS OF THE PARALLEL IMPORTATION APPEALS COMMITTEE

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, after consultation with the Pharmacy and Poisons Board, makes the following Rules—

THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES, 2019

PART I—PRELIMINARY

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Parallel Imported Medicinal substances) Rules, 2019.

Application.

2. These Rules shall apply to medicinal substances which are parallel imported and distributed on the Kenyan market except—

(a) a medicinal substance prepared by a pharmacist in the pharmacy and dispensed without promotion, blood, blood plasma and blood preparations containing cellular elements of blood, or substances such as dental fillings and plates, or surgical preparations such as catgut and plaster of Paris bandages;

(b) non-registered patented medicinal substance for compassionate use;

(c) an orphan medicinal substance; or

(d) non-registered medicinal substance for named patient use and hospitals.

Interpretation.

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

Cap. 244.

"Act" means the Pharmacy and Poisons Act;

"Appeals Committee" means the Parallel Importation Appeals Committee established under rule 48;

"authorized officer" means the registrar, pharmaceutical analyst, pharmaceutical inspector, a medical officer, an inspector of medicinal substances, an administrative officer or a police officer in the rank of Superintendent and above;

"branded generic medicinal substance" means a medicinal substance usually intended to be interchangeable with the originator brand product, manufactured without a licence from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights;

"certificate" means the certificate of parallel importation issued under rule 6;

"country of origin" means a country from which the parallel imported medicinal substance is imported;

"licence" means a licence granted under rule 14 to allow the licensee to carry on parallel importation of a medicinal substance;

"licensee" means a person licensed to engage in parallel importation of a medicinal substance under these rules;

"marketing authorization" means the certificate of registration issued by the competent medicinal substance regulatory authority in the country of origin for the purpose of marketing or free distribution of a medicinal substance after evaluation for safety, efficacy and quality;

"marketing authorization holder" means a person who holds a marketing authorization;

"notification" means the process of entering actual movement and state of each unit of a medicinal substance into the tracing system established under rule 43;

"parallel importation" means the importation into Kenya, by a licensed importer of medicinal substance other than the marketing authorization holder or his or her technical representative of the following medicinal substances which require marketing authorization in Kenya—

(a) patented medicinal substances under section 58(2) of the Industrial Property Act, 2001; No. 3 of 2001.

(b) non-patented medicinal substances; or

(c) branded generic medicinal substances;

"parallel imported medicinal substance" means a medicinal substance imported into Kenya under these Rules;

"pharmacovigilance" means the detection, assessment, understanding and prevention of adverse effects or any other medicinal substance-related problem; and

"risk management plan" means a detailed description of a plan that contains—

(a) a description and analysis of the safety profile of the medicinal substance including a summary of the safety concerns; and

(b) a set of medicinal substance vigilance and risk minimization activities designed to identify, characterize and manage risks relating to the medicinal substance including the assessment of the effectiveness of these activities and interventions.

PART II—CERTIFICATE OF PARALLEL IMPORTATION AND PARALLEL IMPORT LICENCE

Qualification to parallel medicinal substances.

4. A person shall not parallel import a medicinal substance into Kenya unless—

(a) the person is incorporated as a limited liability company under the Companies Act, 2015; No. 17 of 2015.

(b) the person has been granted a certificate of parallel importation; L.N. 147/1981.

(c) the person is licensed to parallel import the medicinal substance;

(d) the medicinal substance has a valid registration in Kenya under the Pharmacy and Poisons (Registration of Drugs) Rules; and

(e) the medicinal substance has a valid market authorization in the country of origin.

Application for a certificate of parallel importation.

5. (1) A person who wishes to undertake parallel importation shall apply, to the Board, for a certificate of parallel importation in the Form 1 set out in the First Schedule.

(2) The application form shall be accompanied by—

(a) a certified copy of the applicant's certificate of incorporation;

(b) a certified copy of the applicant's memorandum and articles of association or its equivalent under the Companies Act, 2015; No. 17 of 2015

(c) the applicant's company profile as may be appropriate for parallel importation of medicinal substances;

(d) a copy of certificate of registration, issued under section 9 of the Act, to the registered pharmacist who shall be at the premises;

(e) a copy of certificate of registration of premises issued under section 23 of the Act;

(f) a copy of wholesale dealer's licence issued under section 27 of the Act;

(g) a copy of manufacturer's licence issued under section 35A of the Act, where applicable;

(h) a copy of certificate of membership of Pharmaceutical Society of Kenya;

(i) such other information as the Board may require from time to time; and

(j) the application fee prescribed in the Second Schedule.

Issuance of certificate of parallel importation.

6. The Board shall consider an application made under rule 5 and where satisfied that all the necessary requirements have been met, issue a certificate of parallel importation to the applicant, within a reasonable time of the applicant lodging the application.

Certificate of parallel importatio not transferable.

7. A certificate of parallel importation issued under rule 6 shall not be transferred, assigned or encumbered in any way.

Validity of certificate of parallel importation.

8. The certificate of parallel importation granted under rule 6 shall expire on 31st December of every year.

Rejection of an application for a certificate of parallel importation.

9. (1) The Board may, within fourteen days of receipt of an application under rule 5, consider and reject an application which in the opinion of the Board—

(a) is substantially defective; or

(b) has not met the requirements of rule 4.

(2) The Board shall communicate the rejection of an application to the applicant within fourteen days of the Board's decision and shall state the reason for the rejection.

Application for renewal of certificate of parallel importation.

10. (1) The holder of certificate of parallel importation may apply to the Board for renewal of the certificate at least three months before the expiry of the certificate.

(2) The application referred to under paragraph (1) shall—

(a) be in Form 1 set out in the First Schedule; and

(b) be accompanied by the renewal fees prescribed in the Second Schedule.

(3) The Board may renew a certificate where—

(a) it is satisfied that the licensee has been operating in compliance with these Rules; and

(b) the certificate holder has fulfilled its tax obligations and submitted a current certified copy of a tax compliance certificate or its equivalent as issued by the Kenya Revenue Authority.

(4) Where the holder of a certificate submits an application for renewal of a certificate under paragraph (1), the certificate shall be deemed to be valid until the application for renewal is determined.

(5) A holder of a certificate of parallel importation who does not wish to renew a certificate shall inform the Board and specify the parallel imported medicinal substances within its possession and how it intends to dispose of the substances.

(6) The certificate of parallel importation of a holder who fails to apply for renewal of the certificate within the period prescribed in paragraph (1) shall, at the expiry of its validity, be deemed to have lapsed and the holder shall not parallel import or sell such medicinal substances or purport to do anything in relation to the medicinal substances in Kenya.

(7) A person who contravenes paragraph (6) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding ten years, or to both.

Application for parallel import licence.

11. (1) The holder of a certificate of parallel importation shall apply to the Board for a license to parallel import a medicinal substance in Form 2 set out in the First Schedule.

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

(a) copies of the package insert and patient information leaflet translated into English or Kiswahili, where available;

(b) an appropriately labelled sample of the medicinal substance to be imported;

(c) information on the exporter, stating whether it is a manufacturer, packer, re-packer or wholesaler;

(d) a statement of justification for importation of the medicinal substance including but not limited to the economic advantage of reduced price;

(e) evidence that the medicinal substance is covered by an existing market authorization in the country of origin;

(f) an undertaking that the applicant will ensure the continued safety, efficacy and quality of the medicinal substance as determined by the Board in Form 3 set out in the First Schedule;

(g) a written confirmation of the lowest price at which the medicine is currently sold by the marketing authorization holder of the certificate of registration in Kenya dated not more than one month before the date of submission of the application for a parallel import licence;

(h) such other information as may be required by the Board from time to time; and

(i) the application fee prescribed in the Second Schedule.

(3) The marketing authorization holder shall not prevent the importation of a parallel imported medicine into Kenya or its sale on account of holding a certificate of registration or on account of the existence of a patent on such medicine.

Additional requirements by the Board.

12. (1) The Board may, when considering an application made under rule 11, make inquiries and request for such additional evidence and documents as the Board may consider necessary.

(2) The Board shall, within seven working days, specify to the applicant such additional evidence and documents as it may require under paragraph (1).

(3) The Board shall reject an application where an applicant fails to provide additional evidence and documents under paragraph (2).

Board inquiries in country of origin.

13. The Board may, where it considers it necessary—

(a) make inquiries to the authorities in the country of origin of a medicinal substance to ensure that the medicinal substance in question has a valid marketing authorization in the country of origin;

(b) verify manufacturer details, the marketing authorization holder, the complete composition, the shelf life and the storage conditions; or

(c) carry out audits on the importers.

Issuance of licence.

14. (1) The Board may, if satisfied that an applicant has met all the requirements, issue a parallel import licence to the applicant, within a reasonable time of the applicant lodging the application.

(2) The licensee may, upon receipt of a licence, proceed with the importation of the medicinal substance after the medicinal substance has been licensed.

Licence not transferable.

15. A licence issued under rule 14(1) shall not be transferred, assigned or encumbered in any way.

Validity of licence.

16. The licence issued under rule 14(1) shall expire on 31st December of every year.

Rejection of an application for a parallel import licence.

17. (1) The Board may, within fourteen days of the applicant lodging the application under rule 11, reject an application which in the opinion of the Board—

(a) is substantially defective; or

(b) has not complied with the requirements under rule 11.

(2) The rejection referred to under paragraph (1) shall be communicated to the applicant within fourteen days of the Board's decision and shall state the reason for the rejection.

General conditions of parallel import licence.

18. A licensee shall—

(a) take measures to ensure the safe use of the medicinal substance and include them in the licensee's risk management plan;

(b) comply with obligations on the recording or reporting of suspected adverse reactions to the Board;

(c) comply with any other conditions or restrictions with regard to the safe and effective use of the medicinal substance; and

(d) establish an adequate pharmacovigilance system.

Application for renewal of a parallel import licence.

19. (1) A licensee shall apply to the Board for renewal of a licence to parallel import medicinal substances at least three months before the expiry of the licence.

(2) An application under paragraph (1) shall—

(a) be in Form 2 set out in the First Schedule; and

(b) be accompanied with the renewal fees prescribed in the Second Schedule.

(3) The Board may renew a licence where—

(a) it is satisfied that the licensee has been operating in compliance with these Rules; and

(b) the licensee has fulfilled its tax obligations and submitted a current certified copy of a tax compliance certificate or its equivalent as issued by the Kenya Revenue Authority.

(4) Where the licensee submits an application for renewal of a licence under paragraph (1), the licence shall be deemed to continue in force until the application for renewal is determined.

(5) A licensee who does not wish to renew a licence shall inform the Board and specify the parallel imported medicinal substances within its possession and how it intends to dispose of the substances.

(6) The licence of a licensee who fails to submit an application for renewal of license within the period prescribed in paragraph (1) shall, at the expiry of its validity, be deemed to have lapsed and the licensee shall not parallel import or sell such medicinal substances or purport to do anything in relation to the medicinal substances.

(7) A person who contravenes paragraph (6) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Revocation, variation and suspension of parallel import licence.

20. (1) The Board may revoke, vary or suspend a parallel import licence if the Board determines that—

(a) the medicinal substance to which the parallel import licence relates is harmful;

(b) the qualitative or quantitative composition of the medicinal substance is not as described in the application for the parallel import licence or the material supplied with it;

(c) the application or the material supplied with it was incorrect;

(d) there has been a breach of any of the terms of the parallel import licence or a requirement on packaging and leaflets;

(e) a general condition of the parallel import licence has not been fulfilled;

(f) the licensee has not complied with rule 11;

(g) the licensee has ceased to be established in Kenya; or

(h) urgent action to protect public health is necessary, in which case it may suspend the parallel import licence.

(2) A person aggrieved by the decision to vary, revoke or suspend a licence may lodge an appeal to the Appeals Committee within thirty days from the date of the decision.

Suspension of use, sale, supply or offer for sale or supply of medicinal substance.

21. (1) The Board may suspend the use, sale, supply or offer for sale or supply within Kenya of a medicinal substance or batches of a medicinal substance to which a parallel import licence relates if the Board determines that—

(a) the medicinal substance to which the parallel import licence relates is harmful;

(b) the positive therapeutic effects of the medicinal substance do not outweigh the risks of the medicinal substance to the health of patients or of the public;

(c) the medicinal substance lacks therapeutic efficacy, given that therapeutic results cannot be obtained from the medicinal substance;

(d) the qualitative or quantitative composition of the medicinal substance is not as described in the application for the parallel import licence or the material supplied with it; or

(e) there has been a breach of any of the terms of the parallel import licence or a requirement on packaging and leaflets.

(2) The Board shall notify a licensee, in writing, of a suspension under this rule for a specified period that is to take effect from the date specified in the notice and shall state reasons for the suspension.

(3) The Board may, in exceptional circumstances and for such a transitional period as the Board may determine, allow the supply of the medicinal substance to patients who are already being treated with a medicinal substance that is the subject of a suspension under this rule.

(4) A parallel importer shall destroy any expired parallel imported medicines remaining in stock after their expiry date, whether during the duration of the permit or after the parallel importation permit has expired.

(5) A person who contravenes paragraph (4) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

(6) A person aggrieved by a decision made by the Board under this rule may appeal to the Appeals Committee within thirty days from the date of the Board's decision.

Recall of a medicinal substance from the market.

22. (1) The Board shall, in writing, require a licensee whose licence has been revoked or suspended under rule 20 to take all reasonably practicable steps to—

(a) inform wholesalers, retailers, medical practitioners, patients and any other person who may be in possession of the medicinal substance to which the parallel import licence relates of—

(i) the revocation or suspension;

(ii) the reasons for the revocation or suspension; and

(iii) any action to be taken to restrict or prevent the further use, sale, supply or offer for sale or supply of the medicinal substance.

(b) recall from the market in Kenya and recover possession of—

(i) the medicinal substance; or

(ii) the batches of the medicinal substance specified in the notice,

within the time and for the period specified in the notice.

(2) The licensee shall as soon as is practicable inform in writing the marketing authorization holder of the recall of the parallel imported medicinal substance.

(3) A person who contravenes paragraphs (1) or (2) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

PART III—INVENTORY OF PARALLEL IMPORTED MEDICINAL SUBSTANCE

Inventory of parallel imported medicinal substances.

23. The Registrar shall keep an inventory containing—

(a) the names of all the holders of certificates of parallel importation;

(b) the names of all licensees;

(c) all parallel imported medicinal substances; and

(d) such other information as may be determined by the Board from time to time.

Record-keeping obligations.

24. (1) A licensee shall at all times keep manual or electronic records of the origin, imported quantities and batch numbers of the parallel imported medicinal substances.

(2) The licensee shall share the records kept under paragraph (1) with the Board, when required to.

(3) A person who contravenes paragraphs (1) or (2) commits an offence and is liable, upon conviction, to a fine not exceeding two hundred thousand or to imprisonment for a term not exceeding one year, or to both.

PART IV—PHARMACOVIGILANCE

Pharmacovigilance issues.

25. (1) A licensee shall establish a system for handling matters relating to pharmacovigilance including a system for—

(a) identifying and reporting adverse reactions;

(b) a system for safety recalls; and

(c) the implementation of risk management plans and direct healthcare professional communication letters.

(2) For the purposes of this rule—

"direct healthcare professional communication" means a single, additional risk minimisation measure sent by marketing authorization holder to healthcare providers to directly inform healthcare professionals about new and important information about a medicinal substance.

(3) The licensee shall submit periodic safety update reports to the Board twice a year.

(4) A periodic safety update report submitted under paragraph (3) shall contain—

(a) summaries of data relevant to the benefits and risks of the medicinal substance, including results of all studies, with a consideration of their potential impact on the licence for the medicinal substance;

(b) a scientific evaluation of the risk-benefit balance of the medicinal substance; and

(c) data relating to the volume of sales of the medicinal substance and any data the licensee has relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal substance.

(5) A person who contravenes this rule commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

(6) The court may, in addition to the penalty imposed under paragraph (4), order any medicinal substance in respect of which the offence has been committed or which has been used for the commission of such offence to be forfeited.

Additional obligations.

26. In addition to the obligations under rules 23 to 25, a licensee shall—

(a) declare information on its supplier, including the name, location and contacts of each of parallel imported medicinal substance;

(b) take full responsibility of quality, efficacy, safety, potency, and security of parallel-imported medicinal substance;

(c) ensure that the storage conditions, Good Distribution Practice and Good Manufacturing Practice are observed during transport and distribution of parallel imported medicinal substances;

(d) have standard operating procedures;

(e) comply with Pharmacy and Poisons Board guidelines on Good Distribution Practice;

(f) recall and destroy parallel imported medicinal substances if the medicinal substances are determined not to comply with quality, safety or efficacy; and

(g) declare the cost benefit of the medicinal substance to the public.

PART V—PRICING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

Principles of pricing of parallel imported medicinal substances.

27. The following principles shall guide all aspects of pricing of parallel imported medicinal substances—

(a) the economic circumstances prevailing in the country;

(b) the price of the locally available medicinal substance;

(c) the cost of importation or packaging, where applicable;

(d) government policy or directives; and

(e) such principles as may be considered necessary.

Pricing guidelines.

28. (1) The Board shall develop guidelines on the pricing of parallel imported medicinal substances to give effect to rule 27.

(2) A person who contravenes any provision of the guidelines developed under paragraph (1) commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

PART VI—PACKAGING AND LABELLING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

Labelling and packaging guidelines.

29. (1) The Board shall make guidelines on the labelling and packaging of parallel imported medicinal substances.

(2) The guidelines shall provide for the following—

(a) the form and content of the package insert;

(b) the form and content of the patient information leaflet;

(c) the labelling of the parallel imported medicinal substance; and

(d) any other information on labelling and packaging that may be deemed necessary.

(3) Where medicine is to be repackaged in Kenya after importation, the repackaging shall be done at a site approved and licensed by the Board for that purpose.

(4) A person who contravenes any provision of the guidelines commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

PART VII—INSPECTIONS

Places authorized officers may enter.

30. (1) An authorized officer appointed by the Board shall—

(a) carry out regular inspections of premises; and

(b) inspect consignments of medicinal substances at the port of entry.

(2) An authorized officer may, at any reasonable time, carry out regular inspection of premises and consignments of medicinal substances at the port of entry.

(3) Despite paragraph (2), an authorized officer may enter any place in which the authorized officer believes, on reasonable grounds, that any person or persons is in any way contravening these Rules.

(4) The authorized officer entering any premises under this rule shall, if so required, produce for inspection by the person who is or appears to be in charge of the premises his job identification card.

Powers of authorized officers.

31. (1) In order to carry out an inspection in any place pursuant to rule 30, an authorized officer may—

(a) enter and inspect the premises or a port of entry;

(b) take samples of any medicinal substance;

(c) examine any medicinal substance;

(d) require any person in such place to produce for inspection, in the manner and form requested by the officer, the medicinal substance;

(e) open or require any person in the place to open any container or package in the premises;

(f) conduct any test or analysis or take any measurements; or

(g) require any person found in the place to produce for inspection or copying, any written or electronic information that is relevant to the administration or enforcement of these Rules.

(2) The authorized officer shall submit a report to the Board after carrying out an inspection in accordance with paragraph (1).

Use of records.

32. When carrying out an inspection in any place, an authorized officer may—

(a) use or cause to be used any computer system in the place to examine data contained in or available to the computer system that is relevant to the administration or enforcement of these Rules;

(b) reproduce the data in the form of a print-out or other intelligible output and take it for examination or copying;

(c) use or cause to be used any copying equipment in the place to make copies of any data, record or document; or

(d) scrutinize any other record system in use in that place.

Entry of dwelling place.

33. An authorized officer may not enter a dwelling place except with the consent of the occupant or under the authority of a warrant issued under rule 34.

Magistrate court to issue warrant.

34. (1) Upon an *ex parte* application by an authorized officer, a magistrate may, if the magistrate is satisfied by information on oath, issue a warrant authorizing the authorized officer or officers named in the warrant to enter and inspect a dwelling place, subject to any conditions specified in the warrant such as—

(a) the dwelling place is a place referred to in rule 33;

(b) entry to the dwelling place is necessary for the administration or enforcement of these Rule.

(c) the occupant does not consent to the entry, or that entry has been refused or there are reasonable grounds for believing that it will be refused or seeking such consent shall hamper investigations.

(2) The time of such entry shall be between six o'clock in the forenoon and six o'clock in the afternoon of any day of the week.

Use of force.

35. An authorized officer executing a warrant issued under rule 34 shall not use force unless the authorized officer is accompanied by a

police officer of the rank of an inspector and above and the use of force is specifically authorized in the warrant.

Certificate of analysis.

36. An authorized officer who has analysed or examined a medicinal substance or a sample of it, under these Rules, shall issue a certificate and report setting out the results of the analysis or examination.

Assistance of an authorized officer.

37.(1) The owner of a place or the person in charge of a place and every person found in a place to be inspected by an authorized officer under these Rules shall—

(a) provide all reasonable assistance to enable the authorized officer to carry out his or her duties under these Rules; and

(b) furnish the authorized officer with such information as the authorized officer may reasonably require for the purpose for which entry into the place has been made.

(2) The authorised officer shall issue an inspection certificate once satisfied with the inspection.

(3) A person who fails to provide assistance or furnish an authorized officer with the required information commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Obstruction.

38. (1) A person shall not obstruct or hinder, or knowingly make a false or misleading statement to an authorized officer who is carrying out duties under these Rules.

(2) A person who obstructs or hinders, or knowingly makes a false or misleading statement to an authorized officer who is carrying out duties under these Rules commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Seizure.

39. (1) An authorized officer may, during an inspection under these Rules, seize any medicinal substance which or in relation to which the authorized officer believes, on reasonable grounds, that these Rules have been contravened and the authorized officer shall make a full inventory of the substances seized.

(2) The authorized officer may direct that any medicinal substance seized be kept or stored in the place where it was seized or that it be moved to another place.

(3) A person shall not remove, alter or interfere in any manner with any medicinal substance seized unless authorized by an authorized officer.

Order for restoration.

40. (1) Any person from whom a medicinal substance has been seized under rule 39 may, within thirty days after the date of seizure, apply to the Board for an order of restoration.

(2) The Board may order that the medicinal substance seized under these Rules be restored immediately to the applicant if, on hearing the application, the Board is satisfied that—

(a) the applicant is entitled to possession of the medicinal substance seized; and

(b) the medicinal substance seized will not be required as evidence in any proceedings in respect of an offence under these Rules.

Rejection of an application for order of restoration.

41. (1) The Board may, within fourteen days of the applicant lodging the application, reject the application that fails to satisfy the requirements under rule 40(2).

(2) The Board shall communicate the rejection under paragraph (1), in writing, to the applicant and shall state the reason for the rejection.

Appeal.

42. (1) A person aggrieved by the decision of the Board under rule 41 may appeal to the Appeals Committee within thirty days of the Board's decision.

(2) The Appeals Committee may order that the medicinal substance be restored immediately to the applicant if, on hearing the application, the Appeals Committee is satisfied that—

(a) the applicant is entitled to possession of the medicinal substance seized; and

(b) the medicinal substance seized will not be required as evidence in any proceedings in respect of an offence under these rules.

(3) A person aggrieved by the decision of the Appeals Committee may appeal to the High Court within thirty days of the Appeals Committee's decision.

(4) The High Court may order that the medicinal substance be restored immediately to the applicant if, on hearing the application, the High Court is satisfied that—

(a) the applicant is entitled to possession of the medicinal substance seized; and

(b) the medicinal substance seized will not be required as evidence in any proceedings in respect of an offence under these rules.

PART VIII—TRACING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

Establishment of a tracing system.

43. The Board shall establish and maintain a system that ensures that a registered parallel imported medicinal substance can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the health facility, institution or private practice where the medicinal substance is used.

Data matrix of medicinal substances.

44. (1) The tracing system established rule 43 shall contain data matrix of parallel imported medicinal substances provided by the licensees.

(2) The data matrix, in relation to a medicinal substance, shall consist of—

(a) business name;

(b) name of marketing authorization holder;

(c) name of the local technical representative;

(d) date of manufacture;

(e) the batch number;

(f) the serial number; and

(g) the expiry date.

(3) For the purposes of this rule—

"data matrix" means a two-dimensional code in data matrix type or any other suitable code that provides the individualization of each medicinal substance as a safety feature.

Functions of the tracing system.

45. The tracing system established under rule 43 shall be used to—

(a) check the individualization, standards and content of the reported data matrix;

(b) record the appropriate data matrix in the database and reject inappropriate ones;

(c) track the importation, purchase, transfer, consumption, loss and reimbursement of each medicinal substance in the supply chain; and

(d) recall and block transactions unauthorized under these rules and that are not allowed through the system.

Duties of a licensee.

46. The licensee shall—

(a) register each of their medicinal substances on the tracing system;

(b) make notification for matters including purchase, sale, return, importation and deactivation steps of the medicinal substances for expiry date, stealing and decomposition;

(c) make notification of all cancelled activities and transactions carried out on the medicinal substances and confirm the convenient ones and refuse the inconvenient ones;

(d) store for a minimum of five years and submit when required by the Board, written documentation of transactions including production and importation documents, bill of sale, receiving note and prescription; and

(e) immediately inform the Board when the licensee identifies a medicinal substance that is subjected to notification to the tracing system but has not been notified to the system.

Batch recalls.

47. The licensee shall—

(a) keep documents relating to the sale or supply of medicinal products under the licence which may facilitate the recall from sale of medicinal substances in accordance with paragraph (b);

(b) maintain an emergency plan to ensure effective implementation of the recall of a medicinal substance from the market where recall is ordered by the Board.

PART IX— THE PARALLEL IMPORTATION APPEALS COMMITTEE

The Appeals Committee.

48. (1) There shall be an appeals committee to be known as the Parallel Importation Appeals Committee to consider and decide appeals from the decisions of the Board under these Rules consisting of—

(a) the Chairman of the Board who shall be the chairman of the Appeals Committee;

(b) two members of the Board;

(c) one person nominated by the Consumers Federation of Kenya and appointed by the Cabinet Secretary;

(d) one person nominated by the Hospital Pharmacists Association of Kenya and appointed by the Cabinet Secretary;

(e) one person nominated by the Pharmaceutical Society of Kenya and appointed by the Cabinet Secretary;

(f) one person nominated by the Kenya Pharmaceuticals Association and appointed by the Cabinet Secretary; and

(g) one person nominated by the National Quality Control Laboratory and appointed by the Cabinet Secretary.

(2) In appointing the members of the Appeals Committee under paragraph (1)(c) to (g), the Cabinet Secretary shall take into account the gender, regional and other diversities of the people of Kenya.

(3) Any member may at any time, by notice to the Chairperson, resign from office.

(4) Where the office of any members become vacant, whether by death or otherwise, the Chairperson may appoint another person to be a member of the Appeals Committee for the remainder of the term of the member whose vacancy caused the appointment.

(5) The procedures for the conduct of meetings of the Appeals Committee shall be as provided in the Third Schedule.

(6) The Board shall provide secretariat services to the Appeals Committee.

Procedure of Appeals.

49. (1) A person aggrieved by a decision of the Board may, within thirty days of receiving the decision, appeal to the Appeals Committee.

(2) Upon receipt of an appeal, the Appeals Committee, shall consider the appeal and may summarily reject the appeal, if it determines that the grounds of appeal are frivolous or vexatious or do not disclose sufficient reason for interfering with the decision of the Board.

(3) The Appeals Committee may, upon hearing an appeal, affirm or reverse the decision of the Board, or make such other order as the Appeals Committee considers necessary and fit.

(4) Any person who is aggrieved by the decision of the Appeals Committee may within thirty days appeal to the High Court.

PART X—MISCELLANEOUS PROVISIONS

Transition.

50. A person carrying out any activity involving parallel importation of medicinal substances immediately before the coming into force of these Rules shall, within six months from the date of coming into force, take all necessary measures to ensure full compliance with these Rules.

Offences in connection with application of parallel import licence.

51. (1) A person who, in the course of an application for the grant, renewal or variation of a parallel import licence for a relevant medicinal substance—

(a) fails to provide the Board with any information that is relevant to the evaluation of the safety, quality or efficacy of the medicinal substance; or

(b) provides to the Board any information that is relevant to the evaluation of the safety, quality or efficacy of the medicinal substance but that is false or misleading in a material particular,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

(2) In addition to the penalty under paragraph (1), the licence of a person convicted of an offence under this rule shall be revoked for a period of not less three years.

Provision of false or misleading information.

52. (1) A licensee commits an offence if the licensee provides false or misleading information about a medicinal substance that is supplied pursuant to the obligations in these Rules.

(2) A person who contravenes this rule is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

Failure to comply with urgent safety restrictions.

53. (1) A licensee who—

(a) fails to inform the Board that the licensee has taken urgent safety restrictions on the licensee's own initiative; or

(b) fails to implement an urgent safety restriction imposed on the licensee by the Board,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

The offence of use, sale, supply, e.t.c of a suspended medicinal substance.

54. (1) A person who knowingly, or having reasonable cause to believe, that the use, sale, supply or offer for sale or supply is suspended—

(a) sells, supplies or offers to sell or supply the medicinal substance; or

(b) procures the sale, supplies or offers for sale or supply of the medicinal substance,

commits an offence and is liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both.

(2) In addition to the penalty imposed under paragraph (1), the court may order any medicinal substance in respect of which the offence has been committed or which has been used for the commission of such offence to be forfeited.

General offence of breach of provisions in these rules.

55.A person commits an offence if that person—

(a) is the holder of certificate of parallel importation or licensee and fails to comply with any requirement or obligation in these Rules;

(b) contravenes any prohibition in these Rules; or

(c) fails to comply with any requirement imposed on a person by the Board pursuant to these Rules.

FIRST SCHEDULE

Form 1 (r.5 (1), 10(2)(a))

APPLICATION FOR CERTIFICATE OF PARALLEL IMPORTATION OR RENEWAL OF CERTIFICATE OF PARALLEL IMPORTATION

(to be submitted in six copies)

CONFIDENTIAL

The application shall be addressed to the Registrar, Pharmacy and Poisons Board, P.O. Box 27663, Nairobi

Application (Tick as appropriate):

Grant of new certificate of parallel importation		Renewal of certificate of parallel importation		Year	

Please use Block (Capitals) Letters

1. Name of applicant.....

2. Physical and postal address of the company:

(a) City/Town.....

(b) L.R. No.....

(c) Street.....

(d) Building.....

(e) P.O. Box.....

(f) Telephone Numbers.....

(g) E-mail Address.....

3. Date of incorporation .....

4. Certificate of incorporation No.....

5. CR12 search.....

6. Number and date of issue of previous certificate of parallel importation .....

7. The number of employees of the company.....

8. Declaration (by Director/Secretary):

I, the undersigned, hereby declare—

(a) THAT the particulars set out herein are true and correct to the best of my knowledge and belief;

(b) THAT if granted certificate of parallel importation, I shall transact parallel importation of medicinal substances in accordance with the provisions of the Pharmacy and Poisons Act, Cap. 244, these rules and any rules, guidelines or directive as may from time to time be issued by the Board.

Name.....

Signature.....

Date.....

Form 2 (r.11(1), 19(2(a))

APPLICATION FOR LICENCE OR RENEWAL OF PARALLEL IMPORTED MEDICINAL SUBSTANCE LICENCE/CERTIFICATE

(to be submitted in six copies)

CONFIDENTIAL

The application shall be addressed to the Registrar, Pharmacy and Poisons Board, P.O. Box 27663, Nairobi

Application (Tick as appropriate):

Grant of new licence		Renewal of licence		Year	

Please use Block (Capitals) Letters

1. Name of applicant.....

2. Physical and postal address of the company:

   (a) City/Town.....

   (b) L.R.No.....

   (c) Street.....

(d) Building.....

(e) P.O. Box.....

(f) Telephone Numbers.....

(g) E-mail Address.....

3. Certificate of Parallel Importation No. .....

4. Number and date of issue of previous licence .....

5. Details of the medicinal substance to be parallel imported:

(a) Trade Name (*Proprietary Product name*) .....

(b) International Non-Proprietary Name .....

(c) Strength of the Active Pharmaceutical Ingredient per unit dosage of the product .....

(d) Pharmaceutical dosage form and route of administration.....

(e) Packaging/Pack size of the product .....

(f) Visual description of the product.....

(g) Proposed shelf-life of the product.....

6. Registration number of the medicinal substance in Kenya .....

7. Justification for importation .....

8. Declaration (by Director/Secretary):

I, the undersigned, hereby declare—

(a) THAT the particulars set out herein are true and correct to the best of my knowledge and belief;

(b) THAT if licensed, I shall transact parallel importation of medicinal substances in accordance with the provisions of the Pharmacy and Poisons Act, Cap. 244, these rules and any rules, guidelines or directive as may from time to time be issued by the Board.

Name.....

Signature.....

Date.....

Form3 (r.11(f))

LETTER OF UNDERTAKING

(to be submitted in six copies)

CONFIDENTIAL

Registrar,
Pharmacy and Poisons Board,
P.O. Box 27663,
NAIROBI

RE:

We undertake to ensure that all medicinal substances that we parallel import meet the safety, quality and efficacy standards as determined by the Board.

Yours sincerely,

Name and signature of applicant

SECOND SCHEDULE

FEES (r. 10(2(b), 19(2)(b))

1. The following are the prescribed fees for the various licences as outlined in the table.

Type	*Fees (Kshs)*
Application for certificate of parallel importation	
Application for renewal of certificate of parallel importation	
Application fee for a new parallel import licence	
Appeal of rejected application for parallel import licence	
Application for renewal of parallel import licence	

2. Any fee payable under paragraph (1) shall be paid by bankers cheque payable to the Board or by any other means prescribed by the Board.

3. The prescribed fees in paragraph (1) may be reviewed by the Board from time to time.

THIRD SCHEDULE (r. 48)

CONDUCT OF PROCEEDINGS OF THE PARALLEL IMPORTATION APPEALS COMMITTEE

Quorum.

1. (1) The quorum of the Appeals Committee shall be five members, including the chairperson.

(2) Despite paragraph (1), members shall not be allowed to delegate their responsibility to their subordinate officers.

Majority decision.

2. (1) Decisions shall be taken by simple majority.

(2) In case of a tie, the proposal supported by the Chairperson shall prevail, and shall be signed by the members agreeing thereto.

Disclosure of interest.

3. If any member of the Appeals Committee has any interest in any particular proceedings before the Appeals Committee, he or she shall inform the Chairperson who may after considering the interest, appoint another person in his or her place for the purpose of that particular appeal.

Venue.

4. The Appeals Committee shall sit at such a place as it may consider most convenient, having regard to all the circumstances of the particular proceedings.

Rules.

5. Subject to the provisions of this Schedule, the Appeals Committee shall have power to make the rules governing procedures.

Proof of documents.

6. A document purporting to be a copy of an order of the Appeals Committee and certified by the Chairperson to be a true copy thereof shall in any legal proceeding be prima facie evidence of that order.

SICILY K. KARIUKI,
Cabinet Secretary for Health.

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