THE PHARMACY AND POISONS ACT

(Cap. 244)

THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES 2018

ARRANGEMENT OF RULES

Rule

PART III- INVENTORY OF PARALLEL IMPORTED MEDICINAL SUBSTANCE

PART IV- PHARMACOVIGILANCE

PART V- PRICING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

PART VI- PACKAGING AND LABELLING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

PART VII- INSPECTIONS

PART VIII- TRACING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

PART IX- MISCELLANEOUS PROVISIONS

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

THE PHARMACY AND POISONS (PARALLEL IMPORTED MEDICINAL SUBSTANCES) RULES, 2018

PART I- PRELIMINARY

Citation.

1. These Rules may be cited as the Pharmacy and Poisons (Parallel Imported Medicinal substances) Rules, 2018.

Interpretation.

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

Cap. 244.

"Act" means the Pharmacy and Poisons Act;

"Appeals Committee" means Parallel Importation Appeals Committee established under rule 19;

"authorized officer" means the registrar, pharmaceutical analyst, pharmaceutical inspector, a medical officer, an inspector of medicinal substances, an administrative officer or a police officer not below the rank of Superintendent;

"Board" means the Pharmacy and Poisons Board;

"Cabinet Secretary" means the Cabinet Secretary for the time being responsible for matters relating to health;

"certificate of parallel importation" means the certificate of parallel importation granted under rule 7;

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

"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;

"medicinal substance" means any medicine, product, article, or substance, which is claimed to be useful for any of the following purposes:

(a) preventing or interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of the function in human beings or animals;

(b) treating, preventing or alleviating disease or symptoms of disease;

(c) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition

"marketing authorization" means 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 the holder of marketing authorization;

"licensing" means approval granted in accordance with these rules 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;

"notification" means the process of inputting actual movement and state of each unit of a medicinal substance into the tracing system established under rule 46;

"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 should have been granted marketing authorization in Kenya—

No. 3 of 2001.

(a) patented medicinal substances under section 58(2) of the Industrial Property Act, 2001;

(b) non-patented medicinal substances;

(c) generic medicinal substances;

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

"parallel import licence" means a licence granted under rule 15;

"pharmacovigilance" means the detection, assessment, understanding and

prevention of adverse effects or any other medicinal substance-related problem; and

Cap. 244.

"registrar" has the meaning assigned to it under section 2 of the Pharmacy and Poisons Act.

"risk management plan" means a detailed description of a risk management 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 minimisation activities designed to identify, characterise and manage risks relating to the medicinal substance including the assessment of the effectiveness of these activities and interventions.

Application of the rules.

3. (1) These rules shall apply to medicinal substances which are parallel imported and distributed on the Kenyan market but does not include 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.

(2) These rules shall not apply to importation of the following—

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

(b) an orphan medicinal substance;

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

Object and purpose of the Rules

4. The object of these Rules is to provide for parallel importation of medicinal substances into Kenya and administration of parallel imported medicinal substances within Kenya.

PART II- CERTIFICATE OF PARALLEL IMPORTATION AND PARALLEL IMPORT LICENCE

Licensing.

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

No. 17 of 2015.

(a) the person is incorporated as a limited liability company under the Companies Act;

(b) the person has been granted a certificate of importation;

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

(d) the medicinal substance is registered in Kenya under the Pharmacy and Poisons (Registration of Drugs) Rules;

L.N. 147 of 1981.

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

Application for a certificate of parallel importation.

6. (1) An application for a certificate of parallel importation shall be made to the Board in the form set out in the First Schedule accompanied with—

(a) the application fee prescribed in the Fifth Schedule payable to

the Board;

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

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

(d) a certified copy of the applicant's memorandum and articles of association or its equivalent under the Companies Act;

No. 17 of 2015

(e) a copy of certificate of registration of a registered pharmacist issued under section 19 of the Act who shall be at the premises;

Cap. 244.

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

Cap. 244.

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

Cap. 244.

(h) copy of manufacturer's licence issued under section 35A of the Act ;

Cap. 244.

(i) a copy of certificate of membership of Pharmaceutical Society of Kenya; and

(j) such other information as may be required by the Board from time to time.

Issuance of certificate of

7. Where the Board is satisfied

parallel importation.

that all the necessary requirements have been met, the Board shall within a reasonable time of the applicant lodging the application, issue a certificate of parallel importation to the applicant.

Certificate not transferable.

8. The certificate of parallel importation granted shall not be transferred, assigned or encumbered in any way.

Validity of certificate of parallel importation.

9. The certificate of parallel importation granted under rule 7 shall expire on 31st December every year.

Rejection of an application.

10. (1) The Board may, within fourteen days of the applicant lodging the application, reject an application which in the opinion of the Board-

(a) is substantially defective; or
(b) has not complied with the requirements under rule 6.

(2) The rejection referred to under subrule (1) shall be communicated 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.

11. The provisions of Rule 21 relating to the application for renewal of parallel import licence shall apply, with the necessary modifications, to the application for renewal of certificate of parallel importation.

Application for parallel import licence.

12. (1) The holder of a certificate of parallel importation shall apply to the Board for a license to parallel import a medicinal substance in the form set out in the Second Schedule

(2) The application under subrule (1) shall be accompanied with—

(a) the application fee

prescribed in the Fifth Schedule payable to the Board

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

(c) an appropriately labelled sample of the medicinal substance;

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

(e) a statement of justification for importation of the medicinal substance;

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

(g) such other information as may be required by the Board from time to time.

Additional requirements.

13. (1) The Board may, upon review under rule 12, make inquiries and request for such additional evidence and documents as the Board considers necessary when the Board receives an application for parallel import licence.

(2) The Board shall, within seven working days, specify to the applicant such additional evidence and documents

as required under subrule (1).

(3) If an applicant fails to comply with the requirements in this rule, the Board shall reject the application.

Board inquiries in country of origin.

14. The Board may—

(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;

(c) carry out audits on the exporters

Issuance of licence.

15. (1) Where the Board is satisfied that all the necessary requirements have been met, the Board shall within a reasonable time of the applicant lodging the application under rule 12, issue a parallel import licence to the applicant.

(2) The licensee may proceed with the import of the medicinal substance only after the medicinal substance has been licensed.

Licence not transferable.

16. The licence granted shall not be transferred, assigned or encumbered in any way.

Validity of parallel import licence.

17. The licence granted under rule 12 shall expire on 31st December every year.

Rejection of an application.

18. (1) The Board may, within fourteen days of the applicant lodging the

application under rule 12, reject an application which in the opinion of the Board-

(c) is substantially defective; or

(d) has not complied with the requirements under rule 12.

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

Establishment of the Parallel Importation Appeals Committee.

19. (1) The Board shall establish an appeals committee to be known as the Parallel Importation Appeals Committee to consider and decide appeals under these rules.

(2) The composition, membership, powers, procedure of meetings and terms of service of the Parallel Importation Appeals Committee shall be as provided in the Third Schedule to these rules.

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

(4) A person aggrieved by the decision of the Board in regard to an application made under rule 12 may, within thirty days of receiving the decision, appeal to the Appeals Committee against the decision.

(5) The Appeals Committee may, on any appeal, affirm or reverse the decision of the Board, or make such other order as the Appeals Committee considers necessary and fit.

(6) Where the Appeals Committee has received an appeal in relation to an application under rule 12, it shall consider that appeal and, 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, may summarily reject the appeal.

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

General conditions of parallel import licence.

20. The licensee shall—

(a) take measures for ensuring the safe use of the medicinal substance and include them in the risk management plan;

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

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

(d) provide an adequate pharmacovigilance system.

Application for renewal of a parallel import licence.

21. (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) The application referred to under subrule (1) shall—

(a) be in the form set out in the Second Schedule to these rules; and

(b) be accompanied with the renewal fees prescribed in the Fifth Schedule and payable to the Board.

(2) Where the licensee does not wish to renew a licence, it shall inform the Board and indicate the parallel

imported medicinal substances within its possession and how it intends to dispose of the consignment.

(4) Where the licensee fails to submit an application for renewal of license under this rule, its licence shall be deemed to have lapsed and shall not parallel import any medicinal substance into Kenya or sale such medicinal substances or purport to do anything in relation to the medicinal substances.

(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 ten years, or to both.

(6) The Board may renew a licence where—

(a) it is satisfied that the licensee has been operating in conformity 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.

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

Revocation, variation and suspension of parallel

22. (1) The Board may revoke, vary or suspend a parallel import licence

import licence.

if the Board determines that—

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

(b) the medicinal substance's qualitative or quantitative composition 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 is incorrect;

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

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

(f) the licensee has not complied with rule 13 (1) to (3) (additional requirements);

(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.

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

Suspension of use etc of relevant medicinal substance.

23. (1) The Board may suspend the use, sale, supply or offer for sale or supply within Kenya 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, in that therapeutic results cannot be obtained from the medicinal substance; or
(d) the medicinal substance's qualitative or quantitative composition is not as described in the application for the parallel import licence or the material supplied with it;
(e) there has been a breach of a term of the parallel import licence or a requirement on packaging and leaflets.

(2) A suspension under this rule may relate to batches of the medicinal substance.

(3) The Board shall give to the licensee notice in writing of a suspension under this rule for a specified period that is to take effect immediately or from a date specified in the notice and shall also state reasons for the suspension.

(4) Where a medicinal substance is the subject of a suspension under this

rule, the Board may—

(a) in exceptional circumstances; and
(b) 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 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 ten years, or to both.

(6) A person aggrieved by the decision of the Board may lodge an appeal in the prescribed form to the Appeals Committee within thirty days from the date of the Board's decision.

Recall of a medicinal substance from the market.

24. (1) The Board shall give written notice to the person who is, or immediately before its revocation, was the licensee requiring that person to take all reasonably practicable steps to—

(a) inform wholesalers, retailers, medical practitioners, patients and others 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 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.

(5) A person who contravenes subrules (1) and (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 ten years, or to both.

PART III- INVENTORY OF PARALLEL IMPORTED MEDICINAL SUBSTANCE

Inventory of parallel imported medicinal substances.

25. The Registrar shall keep an inventory for—

(a) holders of certificates of parallel importation;

(b) names of licensees;

(c) parallel imported medicinal substances;

(d) such other information as may be determined by the

Board from time to time

Record-keeping obligations.

26. (1) A licensee shall at all times keep either 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 referred to in subrule (1) with the Board.

(3) A person who contravenes this rule 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.

27. (1) The licensee shall have in place a system for handling of pharmacovigilance issues including:

(a) A system for identifying and reporting adverse reactions;

(b) A system for safety recalls; and

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

(2) In this rule the term—

(a) "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, important information about a medicinal substance.

(3) The licensee shall submit twice in a year reports known as periodic safety update reports ("PSURs") to the Board.

(4) Each PSUR 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.

(4) 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.

(5) In addition to the penalty imposed under subrule (4), 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.

Additional obligations.

28. 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, GDP and GMP 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 GDP;

(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.

29. 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;

(e) such additional principle as may be deemed necessary.

Pricing Guidelines

30. (1) The Board shall develop Guidelines on the pricing of parallel imported medicinal substances to give effect to rule 29.

(2) 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 VI- LABELLING AND PACKAGING OF PARALLEL IMPORTED MEDICINAL SUBSTANCES

Labelling and packaging Guidelines.

31. (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;

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

(2) 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 authorised officers may enter.

32. (1) The authorised officers shall—

(i) carry out regular inspections of premises;

(ii) inspect consignments of medicinal substances at the port of entry

(2) The authorised officers of the Board appointed for that purpose may, at any reasonable time, carry out regular inspection of premises and consignments of medicinal substances at the port of entry.

(3) Despite subrule (2), the authorized officers may enter any place in which the authorized officers believe on reasonable grounds that any person or persons is in any way contravening the provisions of this Act.

(3) 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 or her job identification card.

Powers of authorised officers.

33. (1) In carrying out an inspection in any place pursuant to rule

32, 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 this Act.

(2) The authorised officer shall submit a report to the Board after carrying out an inspection referred to under subrule (1).

Use of records.

34. In carrying out an inspection in a place, an authorised 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;
(d) scrutinize any other record system in use in that place.

Entry of dwelling place.

35. An authorised officer may not enter a dwelling place except with the consent of the occupant or under the authority of a warrant issued under rule 36.

Magistrate court to issue warrant.

36. (1) Upon an ex parte application, a magistrate may issue a warrant authorising an authorised officer or officers named in the warrant to enter and inspect a dwelling place, subject to any conditions specified in the warrant, if the magistrate is satisfied by information on oath that—

(a) the dwelling place is a place referred to in rule 35;
(b) entry to the dwelling place is necessary for the administration or enforcement of these rules; or
(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.

37. An authorised officer executing the warrant issued under rule 36 shall not use force unless such an authorised officer is accompanied by a police officer of the rank of an inspector and above and the use of force is specifically authorised in the warrant.

Certificate of analysis.

38. An authorised officer who has analyzed or examined a medicinal substance under these rules, or a sample of it, shall issue a certificate and report setting out the results of the analysis or examination.

Assistance of an authorised officer.

39. (1) The owner of a place inspected by an authorised officer under these rules or the person in charge of the place and every person found in the place shall—

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

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

(2) The authorised officer in subrule (1) shall issue an inspection certificate once satisfied with the inspection.

(3) 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.

Obstruction.

40. (1) A person shall not obstruct or hinder, or knowingly make a false or

misleading statement to an authorised officer who is carrying out duties under 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.

Seizure.

41. (1) During an inspection under these rules, an authorised officer may seize any medicinal substance by means of which or in relation to which the authorised officer believes, on reasonable grounds, that these rules have been contravened and a full inventory shall be made at the time of such seizure by the authorised officer.

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

(3) Unless authorised by an authorised officer, a person shall not remove, alter or interfere in any manner with any medicinal substance seized.

Order for restoration.

42. (1) Any person from whom a medicinal substance has been seized under rule 41 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 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 is not and 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.

43. (1) The Board may, within fourteen days of the applicant lodging the application, reject the application that fails to satisfy the requirements under rule 42 (2).

(2) The Board shall communicate the rejection under subrule (1) to the applicant and shall state the reason for the rejection.

Appeals to the Appeals Committee.

44. (1) A person aggrieved by the decision of the Board 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 is not and will not be required as evidence in any proceedings in respect of an offence under these rules.

Appeals to the High Court.

45. (1) 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.

(2) 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—

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

(d) the medicinal substance seized is not and 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.

46. 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.

47. (1) The system referred to in rule 46 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;

(g) the expiry date

(3) In this rule, the term "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.

48. The tracing system referred to in rule 46 shall perform the following functions—

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

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

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

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

Duties of a licensee.

49. The licensee shall—

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

(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;

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

Batch recalls.

50. 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 from the market of a medicinal substance where recall is ordered by the Board.

PART IX— MISCELLANEOUS PROVISIONS

Transition.

51. A person carrying out any activities involving parallel importation of medicinal substances immediately before the coming into force of these rules shall, within six months from the

coming into force thereof, take all necessary measures to ensure full compliance with these rules.

Offences in connection with application of parallel import licence.

52. A person commits an offence if, in the course of an application for the grant, renewal or variation of a parallel import licence for a relevant medicinal substance, the person—

(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.

(3) A person who contravenes this rule shall, in addition to revocation of his or her licence, be liable, upon conviction, to a fine not exceeding one million shillings or to imprisonment for a term not exceeding two years, or to both, and shall have his or her licence revoked for a period of not less three years.

Provision of false or misleading information.

53. (1) The licensee commits an offence if the licensee provides false or misleading information about 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.

54. (1) The licensee commits an offence if the licensee—

(a) fails to inform the Board that the licensee has taken urgent safety restrictions on the licensee's own initiative;
(b) fails to implement an urgent safety restriction imposed on the licensee by the Board; or

(2) 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.

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

55. (1) A person shall not—

(a) sell, supply or offer to sell or supply the medicinal substance; or
(b) procure the sale, supply or offer for sale or supply of the medicinal substance,

knowing, or having reasonable cause to believe, that such use, sale, supply or offer for sale or supply is suspended.

(3) 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.

(4) In addition to the penalty imposed under subrule (3), 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.

56. (1) A person commits an offence if that person commits a breach of a provision in these rules.

(2) A breach of a provision in these rules includes any—

(a) failure by the holder of certificate of parallel importation or licensee to comply with any requirement or obligation in these rules;

(b) contravention by any person of any prohibition in these rules; or

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

(4) Subrule (1) is without prejudice to any offence established by any other provision in these rules.

General Penalty.

57. A person who commits an offence under these rules for which no penalty is prescribed shall be liable, on conviction, to imprisonment for a term not exceeding one year or a fine not exceeding one million shillings, or both.

Amendment of rule 2 of L.N. 147 of 1981.

58. The Pharmacy and Poisons (Registration of Drugs) Rules are amended by deleting the definition "parallel importation" and substituting therefor the following new definition—

"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 should have been granted marketing authorization in Kenya—

(d) patented medicinal substances under section 58(2) of the Industrial Property Act, 2001;

(e) non-patented medicinal substances;

(f) generic medicinal substances;

FIRST SCHEDULE [r.6]
APPLICATION FOR CERTIFICATE OF PARALLEL IMPORTATION OR RENEWAL OF CERTIFICATE OF PARALLEL IMPORTATION

(to be submitted in sextuplicate)

CONFIDENTIAL

The application shall be addressed to the Registrar, Pharmacy and Poisons Board, P.O. Box 30016, 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…….....

SECOND SCHEDULE [r.12]
APPLICATION FOR LICENCE OR RENEWAL OF LICENCE TO PARALLEL IMPORTED MEDICINAL SUBSTANCE

(to be submitted in sextuplicate)

CONFIDENTIAL

The application shall be addressed to the Registrar, Pharmacy and Poisons Board, P.O. Box 30016, Nairobi

Application (Tick as appropriate):

Grant of new licence		Renewal of licence		Year	

Please use Block (Capitals) Letters

9. Name of applicant……
10. Physical and postal address of the company:
    (h) City/Town…….....
    (i) L.R.No….....
    (j) Street…….....
    (k) Building.....
    (l) P.O. Box…….....…….....
    (m) Telephone Numbers…….....…….....
    (n) E-mail Address…….....…….....
11. Date of incorporation ……...….....
12. Certificate of incorporation No…….……
13. CR12 search……...
14. Number and date of issue of previous licence ……...
15. Name of medicinal substance to be parallel imported……
16. Registration number of the medicinal substance in Kenya……
17. Justification for importation……...
18. 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…….....

THIRD SCHEDULE [r.12]
LETTER OF UNDERTAKING

(to be submitted in sextuplicate)

CONFIDENTIAL

Registrar,
Pharmacy and Poisons Board,
P.O. Box 30016,
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

FOURTH SCHEDULE [r. 19]
PARALLEL IMPORTATION APPEALS COMMITTEE

Appeals Committee.

1. The Appeals Committee shall

consist 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 section (1) (c) to (g), the Cabinet Secretary shall take into account the gender, regional and other diversities of the people of Kenya.

Quorum.

3. (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.

4. (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.

5. 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.

6. 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.

Resignation.

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

Vacancy.

8. 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.

Rules.

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

Proof of documents.

10. 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.

FIFTH SCHEDULE (r. 6, r. 21)

PRESCRIBED FEES

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.