PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES

ARRANGEMENT OF RULES

PHARMACY AND POISONS (REGISTRATION OF DRUGS) RULES

[L.N. 147/1981, L.N. 142/1991, L.N. 192/2010.]

1. Citation

These Rules may be cited as the Pharmacy and Poisons (Registration of Drugs) Rules.

2. Interpretation

In these Rules, **"drug"** means a substance or mixture of substances which can be used for any of the following purposes—

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

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

(c) otherwise 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 that function,

in human beings and animals and includes a substance which can be used as a contraceptive or for the purpose of inducing anaesthesia; but does not include a product prepared by a pharmacist in his pharmacy and dispensed by him 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.

"cosmetics" includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eyes or teeth, and includes deodorants and perfumes;

"import" includes parallel importation; and

"parallel importation" means the importation into Kenya of patented drugs under section 58(2) of the Industrial Property Act, 2001.

[L.N. 192/2010, r. 3.]

3. Control of the manufacture, etc., of drugs

No person shall import, manufacture for sale or sell any drug in Kenya unless that drug has been registered and listed in accordance with the provision of these Rules.

[L.N. 192/2010, r. 4.]

4. Application for registration of drug

(1) An application for registration of a drug shall be in Form 1 in the Schedule.

(1A) An application for registration of parallel imported drugs, poisons, listing of herbal, complementary medicines and cosmetics shall be in form 1 in the Schedule.

(2) In addition to the information required to be furnished in the prescribed form the applicant shall furnish such further information and material as may be required by the Board for the proper evaluation of the drug in respect of which the application is made.

(3) An application for renewal of registration of a drug under rule 7 shall be in Form 1A set out in the Schedule.

[L.N. 142/1991, r. 2, L.N. 192/2010, r. 5.]

(1) An application made under rule 4 shall be accompanied by the following fees—

(a) five thousand shillings if the drug required to be registered has been manufactured outside Kenya; and

(b) one thousand shillings if the drug required to be registered has been manufactured in Kenya.

(2) If the registration is being renewed the applicant shall pay the following fees—

(a) one thousand shillings in respect of a drug manufactured outside Kenya; and

(b) five hundred shillings in respect of a drug manufactured in Kenya.

(3) A fee of five hundred shillings shall be paid for a duplicate copy of the certificate of registration if the original is defaced, damaged or lost and such copy shall bear the words "DUPLICATE COPY".

6. Issue of certificate of registration

(1) The Board shall consider the application made under rule 4, and, if it is satisfied of the safety, efficacy, quality and economic value of the drug, shall register the drug and issue a certificate of registration which shall be in Form 2 in the Schedule.

(1A) The Board shall consider the application made under subrule 4(1)(a) and may, if it is satisfied of the safety, quality, efficacy and economic value of the drugs, register the same, and issue a certificate of registration which shall be in Form 2.

(2) The Board may, while considering a drug for registration under paragraph (1), approve the details as supplied by the applicant or approve it with such amendments as it may deem appropriate in respect of the following particulars—

(a) the name under which the drug may be sold;

(b) the labelling;

(c) the statement of the representations to be made for the promotion of the drug in respect of—

(i) the claim to be made for the drug;

(ii) the route of administration;

(iii) the dosage;

(iv) the contra-indications, the side effects and precautions, if any; and

(v) the package size.

(3) If the Board is not satisfied as to the safety, efficacy, quality or economic value of the drug, it may, after providing an opportunity to the applicant to be heard, reject the application for the registration of the drug and inform the applicant the reasons for rejection in writing.

[L.N. 192/2010, r. 6.]

7. Duration, etc., of certificate of registration

(1) A certificate of registration issued under these Rules shall, unless earlier suspended or revoked, be in force for a period of five years from the date of issue and may thereafter be renewed for periods not exceeding five years at any one time.

(2) If an application for renewal is made before the expiration of the period of validity of a certificate of registration the certificate shall remain in force until the application is

approved; except that where the application for renewal is made after the expiration of the period of validity of the certificate of registration the application shall be considered as a fresh application and the provision of rule 6 shall apply accordingly.

8. Suspension or revocation of certificate of registration

(1) The Board may suspend or revoke a certificate of registration issued under these Rules for such period as the Board may determine.

(2) The powers conferred by subrule (1) shall not be exercised by the Board in respect of any certificate of registration except on one or more of the following grounds—

(a) the matters stated in the application on which the certificate of registration was granted were false or incomplete in a material particular;

(b) that a provision of the certificate of registration has to a material extent been contravened by the holder of the certificate; or

(c) that the premises on which, or on part of which, drugs are manufactured, assembled or stored by or on behalf of the holder of the certificate of registration are unsuitable for the manufacturing, assembling or storage of drugs; or

(d) that new information has been discovered by the Board which renders the drugs unsafe or dangerous.

9. Conditions of registration of a new drug

(1) The Board shall, before registering a new drug for which the research work has been conducted in another country and its efficacy, safety, and quality established in that country, require an investigation on the pharmaceutical, pharmacological and other aspects of the drug to be conducted and clinical trials to be made which are necessary to establish its quality and where applicable the biological availability and its safety and efficacy to be established under local conditions.

(1A) Any person wishing to carry out a clinical trial in the country shall apply to the Board for approval before engaging in such study involving investigational products.

(1B) An application under paragraph (1A) shall be accompanied by the fees set out in Part B of the Second Schedule.

(2) Notwithstanding subrule (1), the Board may register a new drug and require the investigations and clinical trials specified in subrule (1) to be conducted after its registration.

(3) The Board may, if in its opinion it is necessary to do so in the interests of public health, register a new drug for a period of two years.

[L.N. 192/2010, s. 7.]

(1) The Board shall maintain a register containing a record of all the drugs registered.

(2) There shall be payable by entities whose drugs are registered a retention fee in the amount specified in Part A of the Second Schedule.

[L.N. 192/2010, s. 8.]

10. Inspection of premises

The Board may, before issuing a certificate of registration under these Rules, cause the premises in which the manufacturing of the drug is proposed to be conducted to be inspected by inspectors appointed for that purpose, and the inspectors shall have powers to enter the premises and inspect the plant and the process of manufacture intended to be employed in the manufacturing of the drug and make a report to the Board.

11. Offences and penalties

A person who contravenes any of the provisions of these Rules shall be guilty of an offence and shall be liable to a fine not exceeding six thousand shillings or to a term of imprisonment not exceeding six months or to both such a fine and such imprisonment.

FIRST SCHEDULE

[L.N. 147/1981, L.N. 192/2010, r. 9.

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FORM 1 **(r. 4)**

APPLICATION FOR REGISTRATION OF A DRUG

(to be submitted in sextuplicate)

CONFIDENTIAL

PART 1

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

1. Name of Applicant .....
   Business Address .....
   .....
   .....
   Telephone Number .....
2. Name of product to be registered .....
   Type of formulation to be registered .....
   Presentation of the product .....
3. Identification (physical appearance of the product) .....
   .....
   .....
4. Therapeutic classification .....
5. (a) Name and business address of manufacturer .....
   .....
   .....
   .....
   (b) Country of origin .....
6. Registration Number of the product in country of origin and all other countries where it is marketed .....
   .....
7. Is the product authorized to be on the market in the country of origin? If yes, attach a legal certificate of free sale from the registering Authority.
   If no, state the reasons below:
   .....
   .....
   .....
   .....

FIRST SCHEDULE , FORM 1—*continued*

PART II

8. Pharmaceutical Formula of the Product

CONSTITUENT		Quantity	Active or non-Active
Chemical Name	Approved Name (if any)		

PART III

9. The names and structural formula of the active ingredients are as follows:

Approved or Chemical Name	Structural Formula

PART IV

10. Specifications for all the active and non-active raw materials used in the manufacturing process are as follows—

PART V

11. Analytical control procedures which are performed on all active and non-active materials before they are used in the manufacturing process are as follows—

PART VI

12. Analytic control procedures and the frequency with which they are performed during the manufacturing process are as follows—

PART VII

13. Full specifications of final manufactured product are as follows—

PART VIII

14. The analytic control procedures which are performed on the final manufactured product are as follows—

PART IX

15. The inferred shelf-life of the product is as follows—

PART X

16. Summaries of the method of manufacture and packaging are as follows—

PART XI

17. A summary of the experimental details and results of the tests performed on the drug to confirm its pharmacological effects—

PART XII

18. Summary of the experiments and results performed on the drug to confirm its physiological availability.

FIRST SCHEDULE , FORM 1—*continued*

PART XIII

19. Particulars of clinical tests conducted with reference to the efficacy of the use of the drug, with a summary of the nature of the tests, by whom conducted and where, results etc., and with special reference to comparative of controlled clinical tests, double blind tests etc.

The undersigned declares that all the information contained herein is correct to the best of his knowledge and belief.

....

Date of application Signature of applicant

Note:

1. A separate application is required for each drug.
2. A dosage form in a specified strength shall be considered as a drug.
3. Application fees are not refundable.

SCHEDULE

FORM 1A

APPLICATION FOR RE-REGISTRATION OF A DRUG

(to be submitted in sextriplicate)

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

1. Name of Applicant (manufacturer) .....
   Registered physical business address
   (see note 1) .....
   .....
   .....
   Telephone no. (office) .....
2. Name of product to be re-registered .....
   .....
   Type of formulation (see note 2) .....
   .....
   Presentation of the product .....
   .....
   .....
3. Identification physical appearance of the product .....
   .....
4. (a) Therapeutic classification(s) .....
   .....
   .....
   (b) Specific indication(s).....
   .....
   .....

FIRST SCHEDULE, FORM 1A—*continued*

(c) Category (see note 3) .....

.....

.....

5. Name and business address of manufacturer .....

.....

.....

.....

6. Registration number of the product in Kenya .....

.....

Date of first registration .....

7. Has the product been discontinued in any country? .....

.....

If yes, why? .....

.....

.....

8. Have you changed the pharmaceutical formula? .....

If yes, state changes and provide the new formula .....

.....

.....

9. Have you changed the manufacturing procedures? .....

f yes, state the new changes .....

.....

.....

10. Have you made any other changes in quality control of finished products, analytical procedures and packaging specifications? .....

If yes, state new specifications .....

.....

.....

11. Provide recent (5-10 years) pharmacological, physiological, clinical, toxilocological and bioavailability data (see note 4) .....

.....

.....

.....

.....

12. We the undersigned hereby declare that all the information contained herein is correct to the best of our knowledge:

	Name	Signature	Qualifications	Date
(a) Quality Control Manager	.....	.....	.....	.....
(b) Production Manager	.....	.....	.....	.....
(c) Registration Officer	.....	.....	.....	.....

(see note 5)

Notes.—

(1) for foreign manufacturers give your local agents contacts;

(2) tablet, capsule injections;

FIRST SCHEDULE, FORM 1A—*continued*

(3) prescription only medicine (POM), over the counter medicine (OTC), pharmacy medicine (P), general sales (GS);

(4) for veterinary products, provide residue levels in milk and meat;

(5) for (c) local manufacturers, local agents — the company pharmacist is to sign;

(6) a separate application is required for each drug;

(7) reapplication fee is not refundable;

(8) a dosage form in a specific strength shall be considered as a drug;

(9) applicants are notified that any false information given in the application may lead to fines and refusal of subsequent registration of products;

(10) each reapplication must be accompanied by six samples of the smallest commercial pack.

Date ....

Signature of Applicant

FORM 2 **(r. 6.)**

PHARMACY AND POISONS (REGULATION OF DRUGS) RULES

REGISTRATION OF DRUGS CERTIFICATE

Number .....

It is hereby certified that the medicine (drug) as described hereunder has been registered subject to the conditions indicated hereunder—

1. Approved name .....
2. Trade name under which marketed .....
   .....
   .....
   .....
3. Registration No. .....
4. Active ingredients and quantities per unit .....
   .....
5. Form of preparations .....
6. Condition under which medicine is registered .....
   .....
7. Name and business address of manufacturer .....
   .....
8. Registered in the name of .....
   .....
   Business address .....
9. Date of registration .....
10. Expiry date of registration .....

....

Date Registrar, Pharmacy and Poisons Board

SECOND SCHEDULE

[L.N. 192/2010, rr. 52(b), 9(1B).]

A

	Fees (USD)
Imported product (s)	300
Locally Manufactured products(s)	300
Late application for retention penalty	100
Appeal for rejected application of registration	300

B

Application for clinical trials	1000