(Legislative Supplement No. 14)

LEGAL NOTICE NO. 41

THE PHARMACY AND POISONS ACT

(*Cap.* 244)

IN EXERCISE of the powers conferred by section 44 of the Pharmacy and Poisons Act, the Minister for Health, after consultation with the Pharmacy and Poisons Board, hereby makes the following Rules:—

THE PHARMACY AND POISONS (AMENDMENT) RULES, 1971

1. These Rules may be cited as the Pharmacy and Poisons (Amendment) Rules, 1971.

2. Rule 3 of the Pharmacy and Poisons Rules (hereinafter referred to as the principal Rules) is hereby amended— Cap. 244 (Sub. Leg.).

(*a*) in paragraph (1), by the deletion of the words "a permit" and the substitution therefor of the words "an import permit in form 17 in Schedule VIII to these Rules";

(*b*) in paragraph (2), by the deletion of the words "a permit" and the substitution therefor of the words "an import permit";

(*c*) by the deletion of subparagraph (*a*) of paragraph (3);

(*d*) in paragraph (5), by the deletion of the words "may import Part II poisons without a permit" and the substitution therefor of the words "shall not import Part II poisons without an import permit".

3. The principal Rules are hereby amended by the insertion after Rule 13 of the following—

Pharmaceutical representative's permit.

13A. (1) A representative of a person engaged in the sale and supply of pharmaceuticals containing any poison may, in the course of business, give free samples of such products to persons who may lawfully possess Part I poisons if he—

(*a*) is in possession of a permit issued by the Board in that behalf; and

(*b*) enters the following particulars, at the time of issue, in a book used regularly for the purpose—

(i) the date on which the poison was issued;

(ii) the name and quantity of the poison given; and

(iii) the name and address and signature of the person to whom the poison was given.

(2) Every application for a permit under paragraph (1) of this rule shall be made to the Board in form 18 in Schedule VIII to these Rules and shall be accompanied by a fee of twenty-five shillings in respect of the issue of the permit.

(3) Every permit under paragraph (1) of this rule—

(*a*) shall be in form 19 in Schedule VIII to these Rules;

(*b*) shall expire on the 31st December of the year of issue or on the earlier termination of the employment by the person concerned of the person in respect of whom the permit is issued.

4. Rule 14 of the principal Rules is hereby amended by the deletion of paragraphs (4) and (5) and the substitution therefor of the following—

(4) The person in charge of any such institution shall, not less than once in every three months, carry out, or arrange and be responsible for the carrying out by a medical practitioner, a pharmacist or some other person appointed for the purpose by the person in charge, of an inspection of—

(i) all stores, cupboards and other places where poisons are kept in the institution;

(ii) the methods by which poisons are issued, dispensed and used in the institution; and

(iii) all books and other records whatsoever kept in the institution for the purpose of recording the purchase, issue and use of poisons.

(5) The person carrying out the inspection shall submit copies of his report in form 20 in Schedule VIII to these Rules—

(i) to the person in charge of the institution, if that person has not himself carried out the inspection; and

(ii) to the registrar.

(6) Any person who fails to comply with any provision of this rule shall be guilty of an offence.

5. The principal Rules are hereby amended by the deletion of rule 16 and the substitution therefor of the following—

Manufacture of drugs.

16. (1) No person shall manufacture for sale any drug which is or may be used for the treatment of any human or animal ailment unless he is in possession of a licence for that purpose issued by the Board.

(2) Every application for a licence under paragraph (1) of this rule shall be made to the Board in form 21 in Schedule VIII to these Rules and shall be accompanied by a fee of one hundred shillings in respect of the issue of the licence, which shall be refundable if the licence is not granted.

(3) Upon an application for a licence under this rule, the Board may, in its absolute discretion, refuse to grant the licence, or may grant the licence either unconditionally or subject to such conditions as it may think fit.

(4) A licence under this rule shall be in form 22 in Schedule VIII to these Rules.

(5) In any establishment in which drugs are manufactured, whether for sale or otherwise, for the purpose of the treatment of any human or animal ailment, such manufacture shall be carried out by, or under the supervision of,—

(*a*) a registered pharmacist; or

(*b*) a person having a Fellowship or Associateship of the Royal Institute of Chemistry or an equivalent qualification recognized by the Board.

(6) The Board may, by notice in the Gazette, exempt any establishment or class of establishment from any or all of the provisions of this rule.

(7) Any person who contravenes any of the provisions of this rule, or who fails to comply with any condition of a licence issued thereunder, shall be guilty of an offence.

6. Schedule VIII to the principal Rules is hereby amended—

(*a*) in the table of Forms, by the addition after item 16 of the following—

17. Permit to import Part I poisons (rule 3).

18. Application for pharmaceutical representative's permit (rule 13A).

19. Pharmaceutical representative's permit (rule 13A).

20. Institution inspection report (rule 14).

21. Application for licence to manufacture drugs for sale (rule 16).

22. Licence to manufacture drugs for sale (rule 16).

(*b*) by the addition after FORM 16 of the following—

FORM 17

PERMIT TO IMPORT PART I POISONS

..... (*Name*) of

..... (*Address*)

is hereby authorized to import into Kenya from (name and address of exporters/manufacturers/suppliers) .....

.....

the drugs specified in the Schedule hereto.

This permit is issued subject to the following conditions—

1. The drugs shall be imported by (mode of importation—air, sea, parcel post, etc.) .....
2. The purpose for which the poisons are required .....

.....

3. This permit is valid for the import of these poisons on one occasion only/during the year ending 31st December, 19 ....
4. This permit shall be surrendered to the Customs Officer at the time of importation.

SCHEDULE

Specify the drugs, nature and strength of active ingredients and quantities hereof to be imported.

.....

Registrar, Pharmacy and Poisons Board.

c.c. Commissioner-General of Customs and Excise.

[*Reverse*]

ENDORSEMENT BY CUSTOMS OFFICER AT THE TIME OF IMPORTATION

I hereby certify that the person named overleaf has today imported the consignment thereon specified ex ..... under Customs Entry No. ..... dated .....

PORT STAMP

.....

(Signature of Customs Officer)

Rank .....

.....

(Date)

This permit, when completed must be returned by the Customs Officer to the Director of Medical Services, P.O. Box 30016, Nairobi.

FORM 18

APPLICATION FOR PHARMACEUTICAL REPRESENTATIVE'S PERMIT

I/We .....

of (postal address) .....
being engaged in the sale and supply of pharmaceutical goods, hereby make application that our representative Mr. .....
..... be permitted to possess pharmaceutical goods containing Part I poisons as scheduled below, for the purpose of giving free samples to persons who may lawfully possess such goods.

SCHEDULE

.....
.....
.....

Date ....
(Signature of Applicant)

FORM 19

PHARMACEUTICAL REPRESENTATIVE'S PERMIT

Mr. ..... as representative of ..... is hereby permitted to possess and supply free samples of pharmaceutical goods containing Part I Poisons, as scheduled below, to persons who are authorized to use them in their trade, business or profession as laid down in the Pharmacy and Poisons Act, subject to maintenance of records as required by rule 13A (1) (*b*) of the Pharmacy and Poisons Rules.

SCHEDULE

.....
.....
.....

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

Note.—This permit expires on 31st December, 19 ...., or upon the person named ceasing to be employed as a pharmaceutical representative of the firm stated above.

Fee: Sh. 25.

FORM 20

INSTITUTION INSPECTION REPORT

I, the undersigned of (postal address) .....

have today carried out an inspection of .....
as required by rule 14 of the Pharmacy and Poisons Rules.

The following defects are reported—

1. Storage .....
.....
.....

2. Methodss of Handling .....
.....
.....

3. Records .....
.....
.....

I have the following recommendations to make—
.....
.....
.....

The previous inspection was carried out on .....

Signature .....

Designation .....

Date .....

To: 1. ..... (person in charge of the Institution).

2. The Registrar. Pharmacy and Poisons Board.

FORM 21

APPLICATION FOR A LICENCE TO MANUFACTURE DRUGS FOR SALE

The Registrar, The Pharmacy and Poisons Board .....
.....

I/We .....
of (postal address) .....
having premises situated at .....
and being engaged in the business of .....
hereby apply to manufacture for sale the following drug(s) medicine(s) .....
.....

This/These drug(s)/medicine(s) has/have the following composition .....

The manufacture of the above drug(s)/medicine(s) will be carried out under the direct personal supervision of .....
..... who has the following qualifications .....
The manufacture of the above drug(s)/medicine(s) will be carried out at .....

Date ....
(Signature of Applicant)

Note.—Any change of the person under whose direct personal supervision the manufacture is carried out, whether temporary or permanent, must be notified to the Registrar immediately.

FORM 22

LICENCE TO MANUFACTURE DRUGS FOR SALE

.....
of (postal address) .....
and having premises situated at .....
is hereby licensed to manufacture for sale the following drug(s)/medicine(s) .....
under the direct personal supervision of .....
at .....

Note.—This licence expires on 31st December, 19 .....

Registration No. .....

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

Any change of the person under whose direct personal supervision the manufacture is carried on, whether temporary or permanent, must be notified to the Registrar immediately.

Made this 1st day of March, 1971.

I. E. OMOLO OKERO,
Minister for Health.