

LEGAL NOTICE No. 35

REPUBLIC OF TRINIDAD AND TOBAGO

THE PHARMACY BOARD ACT, CHAP. 29:52

REGULATIONS

MADE BY THE MINISTER UNDER SECTION 40 OF THE PHARMACY BOARD ACT

THE PHARMACY BOARD (SALE OF OTC DRUGS)
REGULATIONS, 2000

1. These Regulations may be cited as the Pharmacy Board (Sale of Citation
OTC Drugs) Regulations, 2000.

2. In these Regulations—

Interpretation

“Act” means the Pharmacy Board Act;

Chap. 29:52

“designated area” means an area allocated in the shop for the
storage of OTC drugs;

“Form” identified by a number means the Form with that
number in the Schedule;

“Inspector” means an Inspector appointed under section 20 of
the Food and Drugs Act or any public officer designated by
the Minister to inspect shops for the purposes of these
Regulations; Chap. 30:01

“licence” means a licence to sell OTC drugs, and “licenced shop”
shall be construed accordingly;

“OTC drugs” or “drugs” means the drugs or devises listed or
described in the Second Schedule to the Act;

“shop” or “shopkeeper” has the meaning assigned to it in the
Act; and, “shop” also includes a shop which is licensed to
sell OTC drugs.

3. (1) The Minister shall cause the premises of a shopkeeper who is
applying for the first time for a licence to sell OTC drugs to be inspected
by an Inspector prior to the grant of the licence. Licence to
shopkeeper to
sell OTC
drugs

(2) The licence under section 31 of the Act authorising a
shopkeeper to sell OTC drugs may only be granted where the premises
are arranged to show that:

(a) the drugs shall be stored in a designated area on racks or
shelves placed not less than sixty centimeters above the
floor and thirty centimeters from the ceiling;

(b) drugs for external use shall be stored separately from drugs for internal use;

(c) all drugs shall be stored in a cool, dry area which is—

(i) well lit and ventilated;

(ii) free from pests and rodents;

(iii) secure from heat, moisture and direct sunlight;

(iv) separate from food, liquor and poisonous substances;

(d) all drugs shall be placed out of the reach of children.

Application
for licence
Form 1 in the
Fifth Schedule
to the Act

4. (1) An application by a shopkeeper to sell OTC drugs shall be made to the Minister in the form set out as Form 1 in the Fifth Schedule to the Act.

(2) The Minister, on receipt of the application, shall forthwith forward it to the Inspector and the Inspector shall, within thirty days from the date of the application, examine the designated area and:

(a) if the designated area conforms with the requirements of regulation 3(2), the Inspector shall within the said thirty days issue to the shopkeeper a Certificate of Approval in the form set out as Form 1 of the Schedule; or

(b) if the designated area does not conform with the requirements of regulation 3(2), the Inspector shall within the said thirty days issue to the shopkeeper a Notice in the form set out as Form 2.

Form 1

Form 2

Appeal to
Minister

5. (1) A shopkeeper who is aggrieved by the Notice issued to him under regulation 4(2)(b) may, by notice in writing, appeal to the Minister.

(2) The Minister, on receipt of the notice of appeal shall, within fourteen days consider the appeal, and after having considered the appeal, he may dismiss or uphold it.

(3) Where the Minister upholds the appeal, he shall so notify the Inspector and the Inspector shall, within seven days of the receipt of such notification, issue to the shopkeeper a Certificate of Approval in the form set out as Form 1 and regulation 7(1) shall apply.

(4) Where the Minister dismisses or upholds the appeal, he shall, within seven days, so inform the shopkeeper in the form set out as Form 3 of the Schedule.

Form 3

(5) A shopkeeper whose appeal has been dismissed by the Minister may appeal to the High Court for judicial review.

6. Where a shopkeeper has complied with the notice issued under regulation 4(2)(b), the Inspector shall issue to him a Certificate of Approval in the form set out as Form 2 of the Schedule and regulation 7 shall apply.

Compliance
with notice

7. (1) A shopkeeper to whom a Certificate of Approval has been issued shall resubmit his application to the County Medical Officer of Health of the County in which the shop is situated, together with the said Certificate of Approval and a receipt from the District Revenue Office, acknowledging payment of the prescribed fee.

Resubmission
of application
to County
Medical
Officer

(2) The County Medical Officer of Health shall, within seven days of the receipt of the application, issue to the shopkeeper a licence in the form set out as Form 2 in the Fifth Schedule to the Act.

Form 2 in the
Fifth Schedule
to the Act

8. A shopkeeper shall display the licence in a conspicuous part of the shop, together with a copy of the Second schedule to the Act.

Display of
licence
Second
Schedule to
the Act

9. (1) A licence is valid for a period of twelve months from the date of issue and may be renewed one month before the expiry date.

Application
for renewal of
licence

(2) A shopkeeper to whom a licence has been granted may, in accordance with subregulation (3), apply to the County Medical Officer of Health for a renewal of the licence.

(3) The application together with a copy of the current licence and the receipt from the District Revenue Office acknowledging payment of the prescribed fee, shall be forwarded to the County Medical Officer of Health and regulation 7(2) shall apply.

10. Notwithstanding that a licence was granted pursuant to regulation 7(2), an Inspector may, at any reasonable time, enter the licenced shop to determine whether the requirements of these Regulations are being maintained.

Inspector may
at anytime
examine
layout of
premises

11. (1) An Inspector who enters any shop to perform his duties under these Regulations shall, if so required, produce his certificate of appointment or designation to the shopkeeper.

Obstructing
an Inspector
in the
performance
of his duties

(2) A shopkeeper shall give the Inspector all reasonable assistance when the Inspector is carrying out his examination of the designated area.

(3) A shopkeeper who obstructs an Inspector from carrying out his duties under these Regulations, is liable on summary conviction to a fine of one thousand dollars.

Packaging
and labelling
of drugs and
devices

12. (1) OTC Drugs originally packed by the manufacturer shall not be divided, subdivided, or otherwise broken, for the purpose of repackaging in larger or smaller quantities for sale.

(2) OTC drugs that are not properly labelled shall not be offered for sale.

(3) Labels shall be affixed to OTC drugs with the following information in the English language:

(a) international non-proprietary names or brand name of the drug;

(b) name and address of manufacturer;

(c) words of caution where applicable;

(d) dosage, form and strength;

(e) contra indications;

(f) expiry date of drug.

Invoices and
bills to be
retained

13. All invoices or bills shall be retained by the distributor or manufacturer and the shopkeeper for a period of not less than two years and shall be made available for inspection from time to time.

Offences,
revocation of,
or refusal to
renew a
licence

14. (1) A shopkeeper who contravenes the provisions of these Regulations is liable on summary conviction to a fine of one thousand dollars where no penalty is prescribed for the offence.

(2) Notwithstanding subregulation (1), the Minister may revoke or refuse to renew a licence where a shopkeeper contravenes any of the provisions of the Act or of the Regulations.

Revocation of
regulation 24
of the
Pharmacy
Board
Regulations

15. Regulation 24 of the Pharmacy Board Regulations is repealed.

Repeal of
Pharmacy
Board
(Amendment)
Regulations
L.N. 5/1999

16. The Pharmacy Board (Amendment) Regulations, 1998 are hereby revoked.

SCHEDULE

FORM I

[Regulations 4(2)(a), (1), (5) and (3)]

REPUBLIC OF TRINIDAD AND TOBAGO

Pharmacy Board Act (Chap. 29:52)

CERTIFICATE OF APPROVAL

FOR THE SALE OF OTC DRUGS

THIS IS TO CERTIFY that I have examined the designated area allocated in the shop owned by

.....
(Name of shopkeeper)

and which is known as/or which is trading as
(Name of shop, if any)

of
(Address of shop)

and I am satisfied that the said designated area conforms with the requirements of regulation 3 of the Pharmacy Board (Sale of OTC Drugs) Regulations, 2000.

I HEREBY RECOMMEND that a licence to sell OTC drugs be granted to the above-named shopkeeper.

.....
(Inspector)

Dated this day of, 20....

FORM 2

[Regulations 4(2)(a), 6(1)]

REPUBLIC OF TRINIDAD AND TOBAGO

Pharmacy Board Act (Chap. 29:52)

NOTICE TO SHOPKEEPER PURSUANT TO REGULATION 4(2)(b) OF THE PHARMACY BOARD (SALE OF OTC DRUGS) REGULATIONS, 2000

To (Shopkeeper)

trading as..... (Name of shop, if any)

at (Address of shop)

TAKE NOTICE that the designated area allocated in your shop for the sale of OTC drugs was, in your presence/or in the presence of (Name of person and status)

and I have found that the designated area does not conform to the following requirements as stipulated in regulation 3 of the Pharmacy Board (Sale of OTC Drugs) Regulations, 2000, namely, regulation 3(2)(a)*, (b)*, (c)*, or (d)*.

AND FURTHER TAKE NOTICE THAT YOU ARE REQUIRED to reconstruct or reconvert the designated area accordingly to conform with the requirements as stipulated in the said regulation 3(2)(a)*, (b)*, (c)*, or (d)*, and thereafter to resubmit your application.

..... (Inspector)

Served on the above named on day of 20.....

(*Delete whichever is inapplicable)

FORM 3

[Regulation 5(4)]

REPUBLIC OF TRINIDAD AND TOBAGO

Pharmacy Board Act (Chap. 29:52)

NOTICE OF APPEAL MADE PURSUANT TO REGULATION 5 OF THE
PHARMACY BOARD (SALE OF OTC DRUGS) REGULATIONS, 2000

To
(Name of shopkeeper)

trading as.....
(Name of shop, if any)

at
(Address of shop)

PLEASE BE ADVISED that your appeal pursuant to regulation 5 has been upheld/dismissed.*

.....
Minister of Health

*(*Delete whichever is inapplicable)*

Dated this day of , 20.....

Dated this 21st day of January, 2000.

H. RAFEEQ
Minister of Health