



Tonga

PHARMACY ACT 2001

No. 6 of 2001



PHARMACY ACT 2001

Arrangement of Sections

Section

PART I - PRELIMINARY	7
1 Short title and commencement.....	7
2 Interpretation.....	8
PART II - THE PHARMACY BOARD	11
3 Pharmacy Board.....	11
PART III - REGISTRATION OF PHARMACISTS AND ASSISTANT PHARMACISTS	12
4 Registers.....	12
5 Application for registration.....	13
6 Registration.....	13
7 Effect of Registration.....	13
8 Provisional registration.....	13
9 Temporary registration.....	14
10 Minister's power to exempt.....	14
11 Holding out.....	14
12 Content of the Registers.....	14
13 Roll Fee.....	15
14 Removal from the register of pharmacists or assistant pharmacists.....	15
PART IV - COMPLAINTS AND DISCIPLINARY PROCEEDINGS	16
15 Making of complaints.....	16

16	Procedure on receipt of a complaint.....	16
17	Dealing with complaints.....	17
18	Conduct of inquiry	17
19	Power to summon witnesses to inquiry	17
20	Power to obtain documents at inquiry	17
21	Evidence of other proceedings	18
22	Additional complaints	18
23	Release of information concerning inquiry	18
24	Authentication of documents	19
25	Representative complainant	19
26	Expedition of inquiries	19
27	Evidentiary certificate	19
28	Certain complaints not to be heard.....	20
29	Consequences of misconduct	20
30	Unfitness	21
31	Removal from registry outside the Kingdom	22
32	Effect of Board's order	22
33	Copy of decision.....	22
34	Review of orders of the Board	23
35	Effect of removal from register or suspension	23
36	Surrender of certificates of registration.....	23
37	Restoration of name	24

PART V - LICENSING OF PHARMACY PREMISES **24**

38	Register of Pharmacy Premises	24
39	Pharmacies to be approved and owners registered.....	25
40	Standards of Pharmacy Premises	25
41	Publications to be kept	26
42	Certificate of registration	26
43	Cancellation or suspension of pharmacy registration.....	26

PART VI - POWERS OF INSPECTION **27**

44	Authorised officers	27
45	Powers of entry, search & seizure	27
46	Power to obtain information.....	29
47	Continuing offence	30
48	Obstruction	30
49	Directions may be issued to secure compliance	31

PART VII - MISCELLANEOUS **31**

50	Contracts etc. void.....	31
51	Wholesale dealing	31
52	Supervised practice	31
53	Automatic vending machines prohibited.....	32

54	Making false or fraudulent representation	32
55	Offence and penalty	32
56	Offences by corporate bodies.....	32
57	Prosecution.....	33
58	Crown to be bound.....	33
59	Regulations	33
60	Repeal and savings.....	33

SCHEDULE **35**

CERTIFICATE OF REGISTRATION	35
CERTIFICATE OF PROVISIONAL REGISTRATION.....	36
LICENCE OF PHARMACY PREMISES	37



PHARMACY ACT 2001

No. 6 of 2001

AN ACT TO REQUIRE THE REGISTRATION BEFORE PRACTICE OF PHARMACISTS AND ASSISTANT PHARMACISTS, TO ESTABLISH THE PHARMACY BOARD, TO PROVIDE FOR THE MAKING OF COMPLAINTS AND DISCIPLINARY PROCEEDINGS, TO REQUIRE THE LICENSING OF PHARMACY PREMISES AND FOR ANCILLARY PURPOSES

I assent,
TAUFA'AHAU TUPOU IV,
21st September, 2002.

[11th July, 2001]

BE IT ENACTED by the King and Legislative Assembly of Tonga in the Legislature of the Kingdom as follows:

PART I—PRELIMINARY

1 Short title and commencement

This Act may be cited as the Pharmacy Act 2001, and shall come into force on a date to be proclaimed by His Majesty in Council.

2 Interpretation

In this Act, unless the context otherwise requires—

“**advertisement**” means an advertisement—

- (a) published in a newspaper, magazine or other publication;
- (b) placed in a circular, hand bill, poster or other notice;
- (c) made orally or by any means of producing light or sound;
- (d) made using a form of electronic communication or utilising an application of information technology, including an advertisement placed on the internet; or
- (e) made in any other manner;

“**assistant pharmacist**”, means a person who is duly registered as such under this Act;

“**automatic machine**” means any machine or mechanical device used or capable of being used for the purpose of selling or supplying goods without the personal manipulation or attention of the seller or supplier, or his employee, or other agent at the time of sale or supply;

“**board**” means the Pharmacy Board established under section 3(1);

“**conduct**” means any act or omission;

“**Council**” means the Health Practitioners Review Council established under the Health Practitioners Review Act 2001;

“**dentist**” means a person who is duly registered as such under the Medical and Dental Practice Act 2001;

“**dispensing**” in relation to a drug, means supplying that drug in accordance with a prescription given by a registered medical practitioner, a registered dentist, a veterinary practitioner or such other health practitioner as it duly [??] by law to prescribe drugs;

“**drug**” includes any product defined as a medicinal drug in the Therapeutic Goods Act 2001;

“**health officer**” means a person who is duly registered as such under the Medical and Dental Practice Act 2001;

“**medical practitioner**” means a person who is duly registered as such under the Medical and Dental Practice Act 2001;

“**medicinal drug**” means any substance whether of animal, plant or synthetic origin (not being a therapeutic device) which is used internally or externally in humans or animals for—

- (a) preventing, diagnosing, curing or alleviating disease, ailment, defect or injury;

- (b) influencing, modifying or inhibiting a physiological process;
- (c) testing susceptibility to a disease or ailment;
- (d) influencing, controlling or preventing conception;
- (e) testing for pregnancy;
- (f) the replacement or modification of parts of the anatomy, but not any product the principal use of which is cosmetic;

“**midwife**” means a person who is duly registered as such under the Nurses Act 2001;

“**Minister**” means the Minister of Health;

“**narcotic drugs and psychotropic substances**” are as defined in the Therapeutic Goods Act 2001;

“**nurse**” means a person who is duly registered as such under the Nurses Act 2001;

“**pharmacist**” means a person who is duly registered as such under this Act;

“**pharmacy**” means the physical facility used for the practice of pharmacy and which is licensed under this Act;

“**Pharmacy Board**” means the Board established under section 3(1);

“**practice of pharmacy**” means—

- (a) responsibility for preparing, storing, distributing and controlling medicinal drugs in a pharmacy;
- (b) compounding a medicinal drug;
- (c) dispensing a medicinal drug;
- (d) selling a medicinal drug;
- (e) disseminating information on health education and health promotion, in general, and on the rational use of medicinal drugs, in particular;
- (f) subdividing or breaking up a manufacturer's original package of a medicinal drug for the purpose of re-packaging the drug in larger or smaller quantities for re-distribution or sale by retail;
- (g) operating a pharmacy insofar as the operation relates to the practice of pharmacy; and
- (h) supervising the practice of pharmacy;

“**prescription**” means the written order of a dentist, dental officer, health officer or medical practitioner for the supply of a drug or poison to any person or of a veterinary practitioner for the supply of a drug or poison to

any animal which complies with the requirements of Part VI of the Therapeutic Goods Act 2001;

“Principal Pharmacist” means the Principal Pharmacist of the Ministry of Health or person acting for the time being in such position;

“professional misconduct”, in relation to a pharmacist or assistant pharmacist, includes—

- (a) any conduct that demonstrates a lack of adequate—
 - (i) knowledge;
 - (ii) skill;
 - (iii) judgment; or
 - (iv) care;
- (b) by the pharmacist or assistant pharmacist in the practice of pharmacy as the case may be, whether by act or omission:
 - (i) contravening a provision of this Act or the regulations;
 - (ii) contravening a registration condition imposed by the Board;
 - (iii) contravening an order made or a direction given by the Board;
 - (iv) being an habitual drunkard or being addicted to any deleterious drug; and
- (c) any other improper or unethical conduct relating to the practice of pharmacy;

“register” means the register of pharmacists or the register of assistant pharmacists or the register of licensed pharmacies, as appropriate, maintained by the Board in pursuance of Parts III and V of this Act;

“Registrar” means the person designated under section 3(9) of this Act;

“supply” with its cognate expressions includes to sell, or to agree to sell, to offer, advertise, have in possession for any such purposes, expose, transmit, convey, deliver, make or prepare for sale, or hire or to exchange or dispose of for any consideration whatsoever, or to transmit, convey or deliver in pursuance of a sale, exchange or disposal as aforesaid;

“supply by wholesale”, in relation to a substance or goods, means—

- (a) supply of the substance or goods for the purposes of re-supply; or
- (b) supply of an ingredient for the purposes of incorporation in the substance or goods;

and includes supply of the substances or goods in wholesale quantities for use—

- (c) in a public institution; or
- (d) in connection with the carrying on by persons, in circumstances required by this Act or the regulations, of any activity so required.

PART II - THE PHARMACY BOARD

3 Pharmacy Board

There shall be established for the purposes of this Act a Board to be called the Pharmacy Board.

- (2) The functions of the Board shall be —
 - (a) to register pharmacists, assistant pharmacists and to licence pharmacies;
 - (b) to deal with matters relating to disciplinary inquiries and the cancellation, suspension, withdrawal and restoration of registration of pharmacists and assistant pharmacists and the licensing of pharmacies;
 - (c) to set standards for the education and training of pharmacists and assistant pharmacists;
 - (d) to ensure maintenance of the required standards of practice and conduct among pharmacists and assistant pharmacists and to promote the development of guidelines and codes of conduct;
 - (e) to advise the Minister on any matter relating to pharmacists and assistant pharmacists; and
 - (f) to review the implementation of the Act, the regulations, guidelines and codes of conduct and to propose any changes or modifications, as may be deemed necessary.
- (3) The Board shall consist of the following members —
 - (a) the Principal Pharmacist;
 - (b) the Registrar;
 - (c) a pharmacist in private practice nominated by the Minister;
 - (d) a pharmacist employed by the Ministry of Health designated by the Minister;
 - (e) an assistant pharmacist nominated by the Minister
 - (f) a lay member nominated by the Minister.
- (4) When holding an inquiry under PART IV, the Board shall co-opt a senior law practitioner to sit on the Board for the purpose of hearing the inquiry.

- (5) The members nominated or designated by the Minister under subsections (3)(c), (d), (e) and (f) shall hold office for a period of two years and shall be eligible for re-appointment.
- (6) The nomination of any member may be cancelled by the Minister, and another person may be nominated in place of such member for the remaining period of office.
- (7) Any nominated member may resign by giving notice of such resignation to the Minister, and he may nominate another person for the remaining period of office.
- (8) The Principal Pharmacist shall be the chairman of the Board.
- (9) The Minister shall designate, from the staff of Ministry of Health, a Registrar who shall also perform the duties of the Secretary of the Board, and such officers as are necessary for the implementation of the Act.
- (10) The seal of the Board shall be kept in the custody of the Registrar and shall be affixed by the Registrar or any other officer duly by the Board to documents to be sealed by the Board.
- (11) The Board shall determine the procedures and rules governing its meetings.
- (12) The Board shall meet as required and shall report to the Council by way of provision of the Minutes of the Board Meetings.
- (13) The Board shall prepare annually a report of its activities during the preceding twelve months and this report shall be made to the Minister.
- (14) The Board has the authority to summon and compel the attendance of any person while conducting complaints and disciplinary proceeding under PART IV.
- (15) An act in good faith, by the Minister, Registrar, chairman or any Board member shall not subject that person to any liability.

PART III - REGISTRATION OF PHARMACISTS AND ASSISTANT PHARMACISTS

4 Registers

- (1) For the purposes of and Act, the Board shall maintain a register of pharmacists and a register of assistant pharmacists.
- (2) The registers may be kept by electronic means.

5 Application for registration

The Board shall determine the form in which applications for registration as a pharmacist or assistant pharmacist shall be made.

6 Registration

- (1) A person shall be entitled to be registered as a pharmacist or assistant pharmacist if he holds the qualification for registration prescribed by regulation.
- (2) Where a person applies to be registered as a pharmacist or assistant pharmacist and the Board decides that he is entitled to be so registered, the Board shall grant him a certificate of registration in Form 1 prescribed in the Schedule.
- (3) Where a person has ceased to be registered as a pharmacist or assistant pharmacist for a consecutive period of 5 years, whether within or outside the Kingdom, the Board may refuse to register him unless he has passed such oral or written examination or carried out such training, at a standard considered satisfactory to the Board, as the Board considers appropriate.

7 Effect of Registration

A person duly registered under this Act shall be entitled to engage in the practice for which he is so registered pursuant to this Act.

8 Provisional registration

- (1) Where a person has applied for registration as a pharmacist or assistant pharmacist, the chairman of the Board may, if satisfied that person has the requisite qualification and experience, and on payment of the prescribed fee, grant to that person a certificate of provisional registration in Form 2 prescribed in the Schedule.
- (2) Where a person has obtained a certificate of provisional registration the person shall be deemed to be registered under the Act until —
 - (a) the date stated in the certificate, or
 - (b) such later date as may be fixed by the Board,which date shall, in either case, be not later than three months after the granting of the certificate.
- (3) The Board may, at any time before the date so stated or fixed, cancel a certificate of provisional registration.

- (4) Upon the cancellation of a certificate of provisional registration, the holder of the certificate shall no longer be deemed to be registered.
- (5) If a person to whom a certificate of provisional registration has been granted becomes registered before the date stated or fixed pursuant to subsection (2), the registration shall, unless otherwise decided by the Board, date from the granting of the provisional certificate.

9 Temporary registration

The Registrar, subject to the approval of the chairman of the Board, may register pharmacists and assistant pharmacists who are registered as such in another jurisdiction, for up to 3 months. The Board shall prescribe the fee payable for such temporary registration.

10 Minister's power to exempt

The Minister may, subject to such conditions as he thinks fit, exempt in writing members of short-term visiting specialist health teams or individual short-term visiting pharmacists or assistant pharmacists, from the requirements of this Act.

11 Holding out

- (1) No person, except a pharmacist or assistant pharmacist, shall —
 - (a) represent or hold out, express or by implication, that he is entitled to engage in the practice of pharmacy;
 - (b) use any sign, emblem, title or advertisement implying that the person is a pharmacist or assistant pharmacist; or
 - (c) use the title pharmacist or assistant pharmacist or any similar designation or abbreviation implying that he is registered as a pharmacist or assistant pharmacist.
- (2) Any person who contravenes this section commits an offence and upon conviction shall be liable to a fine not exceeding \$10,000 or 5 years imprisonment or both.

12 Content of the Registers

A person shall be registered by entering in the appropriate register —

- (a) the name of the person;
- (b) the date of birth of the person;
- (c) the person's professional address in the Kingdom or, if the person has no professional address the person's place of residence;

- (d) particulars of the qualifications entitling the person to be registered;
- (e) the registration number allocated to the person;
- (f) the date of registration;
- (g) any condition to which the person's registration is subject; and
- (h) such other particulars, if any, as are prescribed.

13 Roll Fee

- (1) Every pharmacist or assistant pharmacist shall, on or before the to the on or before the thirty-first day of October in each year (which day is this section referred to as the “prescribed day”) pay to the Registrar a roll fee fixed by the Board for the year commencing on the first day of January next following the prescribed day.
- (2) The pharmacist or assistant pharmacist shall furnish particulars of his address for entry in the register and such other particulars as may be prescribed.
- (3) If the person does not pay the roll fee referred to in subsection (1) on or before the prescribed day in any year, the Board shall forthwith notify the person by letter addressed to him at the address appearing in the appropriate register that if the fee be not paid before the end of the first working day of the next calendar year the person's name shall be removed from the register as from the next day.
- (4) If the name of a pharmacist or assistant pharmacist has been removed from the register under this section, the Board shall, upon application in writing and upon being satisfied that the person is of good character, restore the person's name to the register upon payment of the outstanding roll fee and a reinstatement fee fixed by the Board.

14 Removal from the register of pharmacists or assistant pharmacists

- (1) After due inquiry, as laid down in PART IV, the Board may direct that the name and other particulars of a pharmacist or assistant pharmacist be removed from the appropriate register if:
 - (a) the person is convicted of an offence under this Act or under any other legislation relating to drugs;
 - (b) the person has obtained registration by fraud or misrepresentation;
 - (c) the qualification on the basis of which registration was awarded is withdrawn or cancelled by the authority which awarded it;
 - (d) the person is guilty of unsatisfactory professional conduct or professional misconduct which, after due inquiry by the Board,

- renders the person unfit to be a pharmacist or assistant pharmacist;
or
- (e) the person's name has been removed from a register of pharmacists or assistant pharmacists in another jurisdiction having been found guilty of unsatisfactory professional conduct or professional misconduct.
- (2) The Board may suspend the registration of a pharmacist or assistant pharmacist pending investigations and disciplinary inquiry.

PART IV - COMPLAINTS AND DISCIPLINARY PROCEEDINGS

15 Making of complaints

Any person may make a complaint in writing to the Registrar that a pharmacist or assistant pharmacist —

- (a) has been convicted in the Kingdom or elsewhere of an offence involving fraud, drugs or dishonesty;
- (b) has been guilty of unsatisfactory professional conduct or professional misconduct;
- (c) does not have sufficient physical or mental capacity to carry on practice as a pharmacist or assistant pharmacist; or
- (d) is not of good character.

16 Procedure on receipt of a complaint

- (1) The Registrar shall refer any complaint to the Board.
- (2) The Board may require the complainant to provide further particulars of the complaint and may make such preliminary inquiries concerning the complaint as it thinks fit.
- (3) The Board shall inform the pharmacist or assistant pharmacist against whom the complaint is made of the particulars of the complaint and invite that person to make, within such time as the Board specifies in the notice, such representations to the Board with respect to the complaint as he thinks fit.
- (4) The Board is required to consider any representations made to it within the time specified in its notice.

17 Dealing with complaints

The Board may decide at any time in relation to a complaint that it will —

- (a) deal with the complaint at a meeting of the Board;
- (b) conduct an inquiry into the complaint; or
- (c) decline to deal with or dismiss the complaint.

18 Conduct of inquiry

If the Board decides to conduct an inquiry into a complaint —

- (a) the Board, in conducting the inquiry, shall sit as in open court unless it determines to do otherwise;
- (b) the person against whom the complaint was made is to be afforded an opportunity of defence either in person or by a law practitioner or another adviser;
- (c) the Board is not bound to observe the rules of evidence, but may inform itself of any matter in such manner as it thinks fit; and
- (d) the chairman of the Board is to preside at the inquiry.

19 Power to summon witnesses to inquiry

- (1) The chairman of the Board may summon a person to appear at any inquiry conducted by the Board, to give evidence and to produce such documents as are referred to in the summons.
- (2) The Board may take evidence on oath and require a person appearing at the inquiry to give evidence on oath.
- (3) A person served with a summons shall in the absence of any reasonable excuse attend as required by the summons.
- (4) A person appearing at an inquiry to give evidence shall not, without reasonable excuse, fail to answer a question or to produce statement that he is required to produce.
- (5) Any person who fails to comply with this section commits an offence.

20 Power to obtain documents at inquiry

- (1) The chairman of the Board may, by written notice, require any person to attend before a member of the Board, at a time and place specified in the notice and to produce any document specified in the notice.
- (2) Any person who fails to comply with this section commits an offence.

21 Evidence of other proceedings

The Board may receive and admit, as evidence at any inquiry —

- (a) the judgment and findings of any court (whether civil or criminal) or tribunal made within or outside the Kingdom;
- (b) the verdict or findings of a jury of any such court;
- (c) a certificate of the conviction of any person; or
- (d) a transcript, duly certified by the registrar or clerk of the court or tribunal as correct, of the evidence of witnesses taken in any such court or tribunal;

where the Board is of the opinion that the judgment, findings, verdict, certificate or evidence is or are relevant to the proceedings.

22 Additional complaints

- (1) The Board may at an inquiry deal with one or more complaints about a pharmacist or assistant pharmacist.
- (2) If, during any such inquiry, it appears to the Board that, having regard to any matters that have arisen, another complaint could have been made against the pharmacist or assistant pharmacist concerned —
 - (a) whether instead of or in addition to the complaint which was made; and
 - (b) whether or not by the same complainant,the Board may take that other complaint as having been referred to it and may deal with it at the same inquiry.
- (3) If another complaint is taken to have been referred to the Board under subsection (2) the complaint may be dealt with after such an adjournment (if any) as is, in the opinion of the Board, just and equitable in the circumstances.

23 Release of information concerning inquiry

- (1) The chairman at any inquiry conducted by the Board may, on the request of a complainant, the pharmacist or assistant pharmacist concerned, or any other person, if he thinks it appropriate in the particular circumstances of the case direct the..... all or any of the following matters —
 - (a) the name and address of any witness;
 - (b) the name and address of a complainant;
 - (c) the name and address of a pharmacist;
 - (d) the name and address of assistant pharmacist;

- (e) any specified evidence;
- (f) the subject matter of a complaint;

shall not be published, except in a publication intended primarily for the use of members of the pharmacy, medical or legal professions.

- (2) A direction may be amended or revoked at any time by the chairman.
- (3) A direction under subsection (1) may be given before or during an inquiry, but is not to be given before the inquiry unless notice is given to —
 - (a) the complainant who requested the direction;
 - (b) the complainant, the pharmacist or assistant pharmacist concerned, as appropriate; and
 - (c) such other persons as the chairman thinks fit;of the time and place appointed by the chairman for consideration of the request.
- (4) A person who contravenes a direction given under this section, without reasonable excuse, commits an offence.

24 Authentication of documents

Every document requiring authentication by the Board may be sufficiently authenticated if signed by the chairman of the Board or by a member of the Board authorised to do so by the chairman without the seal of the Board.

25 Representative complainant

At any inquiry, an officer of the Ministry of Health appointed by the Director of Health may, with the consent of the complainant, act for the complainant.

26 Expedition of inquiries

- (1) It is the duty of the Board to conduct inquiries under this Act and to determine those inquiries as soon as is reasonably practicable.
- (2) Without affecting the generality of subsection (1), the Board may postpone or adjourn an inquiry being conducted by it as it thinks fit.

27 Evidentiary certificate

A certificate signed by the Registrar, that —

- (a) a person was or was not a pharmacist or assistant pharmacist as appropriate;
 - (b) the name of a person was removed from the register;
 - (c) a person was suspended from practising pharmacy; or
 - (d) a condition, particulars of which are set out in the certificate, was —
 - (i) imposed on the registration of a person so specified; or
 - (ii) revoked or not in force;
- shall be received by the Board, the Council and all courts as prima facie evidence of its contents.

28 Certain complaints not to be heard

- (1) The Board may decide not to conduct an inquiry, or at any time to terminate an inquiry if —
 - (a) a complainant fails to comply with a requirement made by the Board; or
 - (b) the person about whom the complaint is made ceases to be a pharmacist or assistant pharmacist.
- (2) The Board or Council shall not to conduct or continue any inquiry or any appeal if the pharmacist or assistant pharmacist has died.

29 Consequences of misconduct

- (1) The Board may, if it is satisfied that the subject matter of a complaint against a pharmacist or assistant pharmacist is proved, do any one or more of the following —
 - (a) caution or reprimand the person;
 - (b) order that the person seek medical or psychiatric treatment or counselling;
 - (c) order that such conditions, relating to the person's practice pharmacy, as it considers appropriate, be imposed on the person's registration;
 - (d) order that any authority of that person to prescribe or administer narcotic drugs and psychotropic substances be withdrawn;
 - (e) order that the person complete such educational courses as are specified by the Board;
 - (f) order that the person report on the person's pharmacy practice at the times, in the manner and to the persons specified by the Board;

- (g) impose a fine not exceeding \$1,000;
 - (h) order that the person's registration be suspended for such period not exceeding 12 months as the Board thinks fit;
 - (i) order that the person's name be removed from the register.
- (2) If the registration of a pharmacist or assistant pharmacist is suspended under this section, the Registrar shall note in the register the suspension and its date and cause.
- (3) The Board shall not suspend a person's registration or remove a person's name from the register for having committed an offence if, having regard to the nature of the offence or the circumstances under which it was committed, the Board is of the opinion that it does not render the person unfit in the public interest to be registered as a pharmacist or assistant pharmacist.

30 Unfitness

- (1) Notwithstanding any other provision of this Act, where the Board is satisfied that any applicant for registration under this Act or any pharmacist or assistant pharmacist is, by reason of infirmity, injury, illness, whether mental or physical, unfit to carry on the practice of pharmacy, the Board shall —
- (a) refuse to register the applicant's name in the register;
 - (b) order that the name of the person be removed from the appropriate register; or
 - (c) order that the person be suspended from practice as a pharmacist or assistant pharmacist for such period as may be specified.
- (2) For the purposes of subsection (1) the Board may —
- (a) require an applicant for registration, a pharmacist or assistant pharmacist to be examined by any medical practitioner as may be specified by the Board; and
 - (b) hold such inquiry as the Board thinks fit.
- (3) A failure or refusal by any person required by the Board to be examined in accordance with a requirement of the Board made under subsection (2)(a) may be regarded by the Board as evidence that the person is, by reason of infirmity, injury or illness, whether mental or physical, unfit to carry on the practice of pharmacy.
- (4) Nothing in subsection (1) affects the powers of the Board under any other provision of this Act to refuse an application for registration under this Act or to remove the name of a pharmacist or assistant pharmacist from

the register or to suspend a pharmacist or assistant pharmacist from practice.

31 Removal from registry outside the Kingdom

Where a pharmacist or assistant pharmacist has, while registered under this Act, been —

- (a) removed from the register, or
- (b) suspended from practice,

as a pharmacist or assistant pharmacist for professional misconduct, in some place outside the Kingdom, the Board may order that the pharmacist's or assistant pharmacist's name be removed from the register or that the pharmacist or assistant pharmacist be suspended from the practice of pharmacy for such period not exceeding 12 months, as the Board determines.

32 Effect of Board's order

- (1) An order made by the Board under section 29 or 31 shall take effect one month from the date the order is served personally on the pharmacist or assistant pharmacist, or is sent by registered post by the Registrar to the pharmacist or assistant pharmacist at the address appearing in the register.
- (2) If within such period the pharmacist or assistant pharmacist applies in writing to the Council, for a review of the Board's decision under section 34, the order shall not be effective until the review proceedings have been completed.

33 Copy of decision

- (1) If, under section 29, the Board decides to make an order in respect of a person or decides to caution or reprimand a person, the Board shall, within one month of making its order, provide the person and any person who made a complaint which resulted in the order or decision and such other persons as it considers appropriate, with a copy statement of its decision.
- (2) If the Board makes a decision in relation to a person under any provision of this Act, other than section 29, the person may request in writing that the Board provide the person with a copy of the decision.
- (3) Any such request shall be made within 60 days after the decision to which it relates.
- (4) The Board shall provide a copy of the decision within one month of receipt of such a request.
- (5) A copy of a decision shall —

- (a) set out any findings on material questions of fact;
- (b) refer to any evidence or other material on which the findings were based; and
- (c) give the reasons for the decision.

34 Review of orders of the Board

- (1) Any person aggrieved —
 - (a) by an order made under sections 29 or 31; or
 - (b) by any refusal or failure to register the person as a pharmacist or assistant pharmacist;

may, not later than one month after being served or sent notice of the order in accordance with section 32, or not later than three months after the application for registration was lodged, apply to the Council for review.

- (2) Any such review will be in the nature of a new hearing at which new evidence may be given.
- (3) The Council may make such order as it thinks fit.
- (4) The provisions of this section do not apply to enable an applicant for provisional registration or the holder of a certificate of provisional registration that has been cancelled to apply for a review of the refusal or cancellation of the certificate of provisional registration.

35 Effect of removal from register or suspension

- (1) Where the name of a pharmacist or assistant pharmacist has been removed from the register under this Act, and until the person's name is restored thereto, the pharmacist or assistant pharmacist shall be deemed not to be registered under this Act.
- (2) Where a pharmacist or assistant pharmacist has been suspended from practice as a pharmacist or assistant pharmacist under this Act, the Registrar shall make an entry in the register of that fact and of the date and cause thereof.

36 Surrender of certificates of registration

- (1) Any person whose name is removed from the register, or who has been suspended from practice as a pharmacist or assistant pharmacist or whose certificate of provisional registration has been cancelled, pursuant to the provisions of this Act, shall within 14 days from receipt of the notification

of such removal or suspension or cancellation surrender to the Board any certificate of registration or provisional registration issued to the person under this Act.

- (2) Any person who, without reasonable excuse, contravenes this section commits an offence against this Act and is liable to a fine not exceeding \$200.

37 Restoration of name

- (1) Where the name of any person has been removed from the register (otherwise than under section 13 (3)), or any person has been suspended from the practice of pharmacy, the person's name shall not be terminated before the period for which the suspension was imposed, except by direction of the Board or by order of the Council or by order of a court of competent jurisdiction.
- (2) The Board may, if it thinks fit in any case, direct the Registrar, without fee, or on payment of such fee, not exceeding the current registration fee as the Board may direct, to restore to the register any name removed therefrom and the Registrar shall restore the name accordingly.

PART V - LICENSING OF PHARMACY PREMISES

38 Register of Pharmacy Premises

- (1) For the purposes of this Act, the Board shall maintain a register of licensed pharmacy premises which shall contain particulars of approved premises and registered owners thereof which may be inspected at the office of the Board at any reasonable time.
- (2) The register may be kept by electronic means.
- (3) An application for licensing of a pharmacy is to be made in a form approved by the Board and shall be accompanied by the fees prescribed in the regulations.
- (4) The Board may require any such application to be supported by an affidavit.
- (5) The Board may —
 - (a) reject the application
 - (b) by order, approve the premises and direct that the owner thereof be registered.

- (6) Premises shall not be approved if they fail to comply with the standards prescribed by section 40 and any other standards prescribed for them by regulation. The Board may, by its order, revoke an approval under subsection (5) if the premises concerned are found not to comply with any such standard.

39 Pharmacies to be approved and owners registered

- (1) A person shall not carry on the practice of pharmacy at any premises unless the premises are approved and licensed under section 38(5)(b).
- (2) Any person who, without reasonable excuse, carries on the practice of pharmacy in premises which are not licensed or the owner of which is not registered as owner commits an offence.

40 Standards of Pharmacy Premises

- (1) The following standards for premises are prescribed —
 - (a) at least one doorway allowing direct public access to the premises is to be provided;
 - (b) secure doors, windows and roof are to be provided;
 - (c) the premises are to be equipped with a dispensing area of at least 8 square meters or such lesser area as the Board may approve in a particular case;
 - (d) a refrigerator suitable for the storage of medicinal drugs at appropriate temperatures is to be provided.
- (2) The dispensing area referred to in subsection (1) (c) shall —
 - (a) have adequate lighting and ventilation;
 - (b) have adequate heating facilities for dispensing and compounding medicinal drugs;
 - (c) be equipped with a stainless steel or similarly impervious sink, being a sink that has an impervious surround and is supplied with hot and cold running water;
 - (d) have a dispensing bench that is at least 40 centimetres wide, and of sufficient length to provide not less than 1 square metre of free working space, and that has an impervious covering; and
 - (e) have a safe or vault for secure storage if narcotic drugs or psychotropic substances are kept on the premises.

41 Publications to be kept

- (1) A person carrying on the practice of pharmacy shall keep at all times a copy this Act, together with a copy of the *Therapeutic Goods Act 2001*, and a recent edition of *Martindale -The Extra Pharmacopoeia*, and all published amendments and supplements thereto on the premises.
- (2) Any person who, without reasonable excuse, fails to keep the publications required under this section commits an offence.

42 Certificate of registration

- (1) No person shall display on any premises the title “pharmacy” or any similar title, sign or designation to describe a retail business in medicinal drugs, unless the premises have been licensed as a pharmacy.
- (2) Where premises are licensed under this Act as a pharmacy, the Board shall issue to the owner a licence in Form 3 prescribed in the Schedule.
- (3) In premises registered under this Act as a pharmacy, the licence shall be displayed, at all times, in a conspicuous place in the pharmacy.
- (4) Any person who, without reasonable excuse, contravenes this section commits an offence.

43 Cancellation or suspension of pharmacy registration

- (1) The Board may cancel or suspend the licence in respect of a pharmacy if —
 - (a) a pharmacy is no longer opened on the premises to which the licence relates; or
 - (b) the pharmacy practices at the pharmacy contravene the provisions of this Act or the regulations.
- (2) Before cancelling or suspending the licence, the Board shall cause a notice to be served on the owner of the pharmacy, or in his absence on the person who is in occupation of the pharmacy, to show cause, within such time as is specified in the notice, as to why the registration should not be cancelled or suspended.
- (3) If no cause is shown within the time stipulated in the notice referred to in subsection (2), or if cause is shown but the Board is not satisfied with it, the Board may cancel or suspend the licence.
- (4) The order of the Board under subsection (3) take effect from such date as is specified in the order.

PART VI - POWERS OF INSPECTION

44 Authorised officers

- (1) The Minister may, by notice in the Gazette, prescribe any person or persons of a specified class or description as authorised officers for the purposes of this Act.
- (2) An authorised officer shall, upon request, provide proof that he is an authorised officer.

45 Powers of entry, search & seizure

- (1) For the purposes of this Act, an authorised officer may at all reasonable times —
 - (a) enter any pharmacy or premises in respect of which an application for a licence has been made;
 - (b) enter any premises where medicinal drugs are being kept for retail trade;
 - (c) enter any place, premises or vehicle in respect of which he know or reasonably suspects —
 - (i) is or are being used for the practice of pharmacy; or
 - (ii) have been or are being or are likely to be used by any person in connection with a contravention of this Act;
 - (d) enter any premises where he knows or reasonably suspects that records are kept relating to the practice of pharmacy or relating to a contravention of this Act;
 - (e) in any premises entered by him
 - (i) search for or examine medicinal drugs, articles, equipment or documents and may take possession of any medicinal drugs, articles, equipment or documents, or samples thereof, or make copies of or extracts from records relating to the practice of pharmacy or relating to any matter the subject of an inquiry under this Act;
 - (ii) seize any medicinal drugs, articles, equipment, documents, or samples thereof, or container or package which he reasonably suspects to contain any medicinal drugs, articles or equipment;
 - (iii) open any room, place, container or package that he knows or reasonably suspects contains any medicinal drugs, articles or equipment;

- (iv) question with respect to matters under this Act any person he finds thereon; and
 - (f) make such inquiry and examination as he believes to be necessary or desirable to assist the discharge or exercise of any function or power under this Act or to ascertain whether any contravention of this Act has been, is being or is likely to be committed.
- (2) Subsection (1) does not authorise forcible entry by an authorised officer to any premises except under the authority of a warrant obtained pursuant to subsection (4).
- (3) Unless he has the permission of the occupier of a part of the premises if that part is used as a dwelling, an authorised officer shall not enter that part without a search warrant issued by a Magistrate.
- (4) A Magistrate, if satisfied upon the information of an authorised officer that there is reasonable cause to suspect that any place has been, or is likely to be used in connection with a contravention of this Act, or for the keeping of records relating to a contravention of this Act, may issue a search warrant directing the authorised officer to enter the place specified in the search warrant for the purpose of exercising the powers conferred on an authorised officer by this Act.
- (5) A search warrant issued under this section is, for a period of 1 month from its issue, sufficient authority —
- (a) to the authorised officer to whom it is directed and to all persons acting in aid of the officer to enter the place specified in the search warrant; and
 - (b) to the authorised officer to whom it is directed to exercise in respect of the place specified in the search warrant all the powers conferred on an authorised officer by this Act.
- (6) For the purpose of gaining entry to any place an authorised officer may call in aid such persons as he considers necessary and such persons, while acting in aid of an authorised officer in the lawful exercise of a power of entry, have a like power of entry.
- (7) If an authorised officer has taken possession of records or of other property for the purposes of this Act he may —
- (a) in the case of records, retain them for as long as necessary for those purposes, but the person otherwise entitled to possession of the records if he so requests, is entitled to be furnished as soon as practicable with a copy certified by the authorised officer to be a true copy and such a certified copy must be received in all courts and elsewhere as evidence of the matters contained in it as if it were the original;

- (b) in the case of other property, subject to this Act, retain the property for as long as is necessary for those purposes, and thereafter dispose of it as the court directs.

46 Power to obtain information

- (1) In relation to any matter relevant to the operation or enforcement of this Act, an authorised officer may require a person (either by oral or written requisition) to furnish —
 - (a) any information;
 - (b) any records or a copy thereof,in the person's possession.
- (2) For the purpose of subsection (1), a person is to be taken to be in possession of —
 - (a) information, if the person has the information or is entitled to have access to the information;
 - (b) records, if the person has them in his possession or under his control in any place, whether for his own use or benefit or for another's use or benefit and although another person has the actual possession or custody of the records.
- (3) A requisition made under subsection (1) may require that the information or records or copy therefore be furnished —
 - (a) to the authorised officer or another authorised officer or to an officer of a specified department of the Government;
 - (b) at the place the requisition is made or at another place;
 - (c) forthwith or at, by or within a time specified;
 - (d) in person, or by registered mail or in another manner specified;
 - (e) by means of, or accompanied by, verification in the form of an affidavit;
 - (f) in the case of information, orally or in writing.
- (4) A person must not without reasonable cause —
 - (a) refuse or fail to furnish any information, records or copy as required under this section;
 - (b) in response to a requisition made under this section furnish information records or copies that is or are false or misleading in a material particular.
- (5) If a person records or stores any matter by means of a mechanical, electronic or other device, the duty imposed by this section to produce any

records containing those matters is to be construed as including a duty to produce the matters in written form if that is demanded.

- (6) The duty imposed by this section to produce a copy of any records is to be construed as a duty to produce a clear reproduction.
- (7) An authorised officer may take notes or copies of or extracts from records or a copy of any records produced under this section.
- (8) Any person who fails to furnish information required under this section commits an offence.

47 Continuing offence

If a person commits an offence by failing to furnish information required under section 46 or to produce any records or a copy of any records —

- (a) the obligation to furnish the information or to produce the records or a copy of them, as the case may be, continues until the person complies with the requirement notwithstanding that in a particular case a time was specified at, by or within which compliance was required and that time has passed;
- (b) the person commits a continuing offence in respect of each day after the day of conviction during which the failure to comply with the requisition continues;
- (c) the person is liable to a fine of \$100 for each day during which the offence continues; and
- (d) the person may be prosecuted from time to time in respect of any continuing offence under subsection (2) above.

48 Obstruction

- (1) A person shall not obstruct an authorised officer in the exercise of his powers under this Act.
- (2) For the purposes of this Act, a person obstructs an authorised officer if he —
 - (a) assaults, abuses, intimidates or insults the authorised officer or any other person assisting the authorised officer in the exercise of his powers under this Act;
 - (b) directly or indirectly prevents any person from being questioned by an authorised officer in the exercise of his powers under this Act;
 - (c) in any way obstructs or attempts to obstruct an authorised officer in the exercise of his powers under this Act.

49 Directions may be issued to secure compliance

- (1) If —
 - (a) any pharmacist, assistant pharmacist, medical practitioner, nurse, health officer, pharmacy premises, prescription or other person, place or thing does not comply with the provisions of this Act; or
 - (b) any provision of this Act has not been complied with,an authorised officer may, in writing, direct any person who has contravened the provision by such non-compliance to take within a specified time, not exceeding 14 days, such steps as may be specified to prevent any further contravention and to remedy the matters in respect of which the non-compliance has occurred.
- (2) The issue of a direction under this section does not affect any proceeding under this Act which has been or may be taken for the non-compliance which gave rise to the direction.
- (3) A person to whom a direction is issued under this section and who does not comply with the direction commits an offence.

PART VII - MISCELLANEOUS**50 Contracts etc. void**

- (1) A contract, agreement, undertaking or understanding which is in effect when this Act comes into force is void to the extent to which it is inconsistent with this Act.
- (2) Neither the Crown nor any person is liable to pay any damages or other compensation to any other person in consequence of subsection (1).

51 Wholesale dealing

Nothing in this Act applies to a wholesale dealer who supplies medicinal drugs in the course of supply by wholesale.

52 Supervised practice

Nothing in this Act prevents a person from engaging in the practice of pharmacy, provided such person functions —

- (a) under the direct supervision of a pharmacist or assistant pharmacist;
- (b) in the presence of the pharmacist or assistant pharmacist; and

- (c) in accordance with any other conditions that may be prescribed in the regulations.

53 Automatic vending machines prohibited

Any person who

- (a) installs any automatic machine for the sale or supply of any medicinal drug or allows, permits or suffers any such automatic machine to be so installed;
- (b) sells or supplies to any person or purchases or is supplied with or otherwise obtains any medicinal drug by any automatic machine; or
- (c) allows or permits any person to purchase or be supplied with or otherwise obtain any medicinal drug by any automatic machine;

commits an offence.

54 Making false or fraudulent representation

Any person who, in an application for registration under this Act, makes or produces or causes to be made or produced any false or fraudulent representation, certificate or affidavit, either verbally or in writing, and any person who knowingly aids or assists therein commits an offence and shall be liable on conviction to a fine not exceeding \$1000 or to imprisonment for a term not exceeding 6 months or both.

55 Offence and penalty

Any person who contravenes or fails to comply with any provision of this Act or any regulation made under this Act commits an offence, and on conviction shall, where no other penalty is provided, be liable to a fine not exceeding \$1000, or imprisonment for a term not exceeding 6 months, or both; and in the case of a continuing offence, to a fine not exceeding \$100 for every day or part of a day during which the offence has continued.

56 Offences by corporate bodies

If a body corporate commits an offence against this Act or any regulation made under this Act, each director or other person concerned in the management of the body corporate is also guilty of, and liable to the penalty provided for, that offence unless the director or other person proves that he exercised reasonable diligence to prevent the commission of the offence.

57 Prosecution

- (1) Prosecutions for an offence under this Act may be brought —
 - (a) by or on behalf of the Attorney General;
 - (b) by an authorised officer; or
 - (c) by a member of the police.
- (2) A person referred to in subsections (b) or (c), whether or not a law practitioner, may lay, institute or conduct any charge, information, complaint or other proceedings arising under this Act, subject to any directions issued by the Attorney General.

58 Crown to be bound

This Act binds the Crown.

59 Regulations

The Minister may, with the consent of the Cabinet, make regulations prescribing matters necessary or convenient to be made for carrying out or giving effect to this Act and, in particular, for the following purposes —

- (a) prescribing the duties of the Registrar;
- (b) prescribing the fees payable under the Act and the regulations;
- (c) exempting from the operation of any of the provisions of this Act or the regulations made thereunder such persons or classes of persons as may be specified;
- (d) providing a code of conduct for pharmacists and assistant pharmacists;
- (e) prescribing the qualifications for registration as a pharmacist or assistant pharmacist;
- (f) prescribing the format of any examination to be conducted by the Board in connection with the registration of pharmacists or assistant pharmacists;
- (g) prescribing the grounds on which registration may be suspended; and
- (h) prescribing the procedures to be followed in conducting disciplinary inquiries.

60 Repeal and savings

- (1) All persons who, at the commencement of this Act, are registered in the pharmaceutical section of the Register of Health Practitioners maintained

under the *Health Practitioners Registration Act 1991* shall be deemed to be registered under this Act.

- (2) A reference in any other Act or instrument to a registered pharmacist or assistant pharmacist or a pharmacist or assistant pharmacist registered under the *Health Practitioners Registration Act 1991*, shall be read and construed as a reference to a pharmacist or assistant pharmacist registered under this Act.

SCHEDULE

Form 1

CERTIFICATE OF REGISTRATION

(Pharmacy Act 2001)

(Section 6(2))

Pharmacy Board of the Kingdom of Tonga

This is to certify that the name of

was entered in the Register of Pharmacists or Assistant Pharmacists for the Kingdom of Tonga as a under the Pharmacy Act 2001 on the day of 20.....

Registration No.:.....

.....

Registrar

This Certificate must be retained as evidence that you have been registered in the Kingdom of Tonga.

Form 2

CERTIFICATE OF PROVISIONAL REGISTRATION

(Pharmacy Act 2001)

(Section 8(1))

Pharmacy Board of the Kingdom of Tonga

This is to certify that the name of is provisionally registered as a until the day of 20.....

Registration No.:.....

.....

Chairman

This certificate of provisional registration covers practice until the expiry date shown.

This Certificate must be retained following the expiry date as evidence that you have been provisionally registered in the Kingdom of Tonga.

Form 3

LICENCE OF PHARMACY PREMISES

(Pharmacy Act 2001)

(Section 42(2))

Pharmacy Board of the Kingdom of Tonga

This is to certify that the premises operated as a Pharmacy located at and owned by who is the registered owner was entered in the Register of Licensed Pharmacy Premises on the day of 20.....

Registration No.:.....

.....

Chairman

This Licence must be retained and displayed upon the pharmacy premises.

Passed by the Legislative Assembly this 11 day of July, 2001.