



Tuvalu

**PHARMACY AND THERAPEUTIC
PRODUCTS ACT**

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PHARMACY AND THERAPEUTIC PRODUCTS ACT**Arrangement of Sections****Section**

PART I- PRELIMINARY	5
1 Short Title.....	5
2 Commencement.....	5
3 Purpose and scope	5
4 Interpretation	6
PART II – THE NATIONAL MEDICINES POLICY AND THE NATIONAL DRUGS AND THERAPEUTICS COMMITTEE	11
5 National Medicine Policy	11
6 Establishment of the Committee	11
7 Functions of the Committee	11
8 Procedures of the Committee	12
PART III – SCHEDULING MEDICINES	13
9 Scheduling of medicines	13
PART IV – CONTROLS ON THERAPEUTIC PRODUCTS	14
10 Therapeutic products to be approved by a recognised regulator	14
11 Control of therapeutic products available in Tuvalu	15
12 Powers of licensing authority to prohibit import or supply of therapeutic products	15
13 Donated medicines	16
14 Supply of medicines	16
15 Prescribing, dispensing, and administering prescription medicines.....	17
16 Labelling of dispensed therapeutic products	17
17 Advertising prohibited.....	18
18 Duty to report adverse effects of therapeutic products.....	18
19 Restrictions on prescribing and supplying to individuals	18
20 Prescribing or supplying in contravention of restriction notice	19
PART V – LICENSING	19
21 Licences required	19
22 Register of licences	20
23 Application for licences	20

24	Granting licences	20
25	Mandatory conditions of licence to operate pharmacy	21
26	Term and renewal of licences	21
27	Display of licences.....	22
28	Suspension or cancellation of licences	22
29	Standards of pharmacy premises	23
PART VI – MONITORING AND ENFORCEMENT		23
30	Authorised officers	23
31	Powers of entry, search and seizure.....	23
32	Power to obtain information	25
33	Continuing offence	26
34	Obstruction.....	27
35	Directions may be issued to secure compliance.....	27
36	Making false or fraudulent representation	27
37	Offences by corporate bodies.....	28
38	Prosecutions	28
39	Protection of authorised officers.....	28
PART VII – MISCELLANEOUS PROVISIONS		28
40	Contracts inconsistent with this Act	28
41	Application of the Customs Act 1963.....	29
42	Relationship with the Dangerous Drugs Act 1948.....	29
43	Supervised practice	29
44	Automatic vending machines prohibited	29
45	Regulations	29
46	Savings and transitional provisions	31
47	Repeals.....	32
48	Consequential amendments	32
48	Regulations revoked	32

No table of contents entries found.



Tuvalu

PHARMACY AND THERAPEUTIC PRODUCTS ACT

Act No.006 of 2016

AN ACT TO REGULATE THE SOURCING AND SUPPLY OF THERAPEUTIC PRODUCTS IN TUVALU AND TO CONTROL ACTIVITIES ASSOCIATED WITH THEIR USE

Commencement [27th May, 2016]

PART I- PRELIMINARY

1 Short Title

This Act may be cited as the Pharmacy and Therapeutic Products Act.

2 Commencement

This Act shall come into force on a date appointed by the Minister.

3 Purpose and scope

The purpose and scope of this Act is to:

- (a) regulate the sourcing of therapeutic products into Tuvalu, including the manufacture and import of such products;
- (b) regulate the and supply chain for therapeutic products within Tuvalu, including the sale or supply of therapeutic products by wholesale or retail;
- (c) control other activities associated with the use of therapeutic products, including prescribing, dispensing, operating a pharmacy, administering, compounding, packaging, advertising, disposal, and other related activities.

4 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, handbill, 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;

“administer” means administer to a human being or animal, either—

- (a) orally or by injection or by introduction into the body in any other way; or
- (b) by external application, whether by direct contact with the body or not; and
- (c) every reference in this Act to administering a substance or article is a reference to administering it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some substance in which it is to be administered;

“authorised prescriber” means a medical practitioner or other health professional authorised to prescribe medicines under this Act, and in the case of the prescription of medicines to animals, a veterinarian;

“authorised officer” means an officer designated under section 30 of this Act:

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

“business” includes:

- (a) a professional practice; and
- (b) any activity carried on for reward by any person;

“Chief Dentist” means the person for the time being performing the duties of the Chief Dentist in and for Tuvalu;

“Chief Nurse/Matron” means the person for the time being performing the duties of the Chief Nurse/Matron of Funafuti Hospital in and for Tuvalu;

“Chief Pharmacist” means the person for the time being performing the duties of the Chief Pharmacist in and for Tuvalu;

“Chief Public Health Officer” means the person for the time being performing the duties of the Chief Public Health Officer in and for Tuvalu;

“*Committee*” means the National Drugs and Therapeutics Committee established under Part II of this Act, unless otherwise stated;

“*conduct*” means any act or omission;

“*container*” in relation to therapeutic products, means a vessel, bottle, tube, ampoule, syringe, vial, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the products or is used in its administration but does not include an article intended for ingestion;

“*controlled poison*” means any substance specified in Part 5 of the Tuvalu Medicines Schedule, kept by the Ministry of Health;

“*customs officer*” means an officer appointed under the *Customs Act 1963*;

“*dangerous drug*” has the meaning specified in section 2 of the Dangerous Drugs Act 1948;

“*disease*” includes any injury, ailment, deformity, disorder, or adverse condition, whether of body or mind;

“*Director of Health*” means the person for the time being appointed as head of the Department responsible for health matters in Tuvalu (or employed in an equivalent position);

“*dentist*” means a person who is registered by the Health Professionals Registration Board to practice dentistry in Tuvalu;

“**Dispensing**” includes:

- (a) preparing a medicine (including compounding a medicine) for supply (other than by wholesale), whether in response to a prescription or a request from an individual to be supplied the medicine; and
- (b) packaging and labelling a medicine as part of preparing the medicine for supply other than by wholesale;

“*Essential medicines list*” means the list of medicines selected for use in Tuvalu, by the Committee, because they are the most important and necessary medicines for the health and safety of the majority of the people of Tuvalu;

“*health clinic*” means a clinic on Funafuti or the outer islands of Tuvalu operated or approved by the Ministry of health;

“*Hospital Pharmacy and Central Medical Store*” means the Pharmacy and Medical Store at Princess Margaret Hospital operated and maintained by the Ministry of Health;

“*importer*” means any person by or for whom any therapeutic products are imported; and includes the consignee of the therapeutic products and also includes any person who is or becomes—

- (a) the owner of any therapeutic products; or
- (b) entitled to the possession of any therapeutic products; or
- (c) beneficially interested in any therapeutic products—

on or at any time after the importation of those therapeutic products and before they have ceased to be subject to the control of the Customs in accordance with the Customs Act 1963;

“label” includes any tag, brand, mark or statement in writing on or attached to or used in connection with any container or package containing any substance, material, body or thing referred to in this Act;

“licence” means a licence issued and in force for the purposes of this Act;

“licensing authority” means the National Drugs and Therapeutics Committee established under Part 2 of the Act;

“manufacture”, includes any process carried out in the course of making the product;

“medical practitioner” means a person who is registered by the Health Professionals Registration Board to practice medicine in Tuvalu;

“medical devices” means therapeutic products consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, though it may be assisted in such function by such means;

“Medical Superintendent” means the person for the time being performing the duties of the Medical Superintendent in and for Tuvalu;

“medicine” means any substance whether of animal, plant or synthetic origin (not being a medical device) which is used internally or externally for:

- (a) preventing, diagnosing, curing or alleviating disease, ailment, defect or injury;
- (b) influencing, modifying or inhibiting of physiological processes;
- (c) testing susceptibility to a disease or ailment;
- (d) influencing, controlling or preventing conception;
- (e) testing for pregnancy; or
- (f) the replacement or modification of parts of the anatomy;

“Minister” means the Minister of Health;

“National Medicines Policy” means the policy specified in section 4 of this Act;

“nurse” means a person who is registered as a nurse by the Health Professionals Registration Board to practice nursing in Tuvalu;

“package”, when used in relation to any substance, material, body or thing referred to in this Act, includes every means by which such substance, material, body or thing may, for transport or for carriage or for storage or for supply, be cased, covered, enclosed, contained or packed;

“pharmacist” means a person who is registered as a pharmacist by the Health Professionals Registration Board to practice pharmacy in Tuvalu;

“pharmacist only medicine” means any medicine specified in Part 2 of the Tuvalu Medicines Schedule, kept by the Ministry of Health;

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

“pharmacy only medicine” means any medicine specified in Part 3 of the Tuvalu Medicines Schedule, kept by the Ministry of Health;

“pharmacy technician” means a person who is authorised by the Ministry of Health to practice as a pharmacy technician in Tuvalu;

“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;

“premises” includes any shops, buildings, pharmacies, permanent or temporary premises, ships, aircraft and vehicles;

“prescription” means the written order of an authorised prescriber for the supply of a medicine to any person;

“prescription medicine” means any medicine specified in Part 1 of the Tuvalu Medicines Schedule, kept by the Ministry of Health;

“Recognised regulator” means a therapeutic products regulator recognised by the Ministry of Health whose decisions are recognised for the purpose of ensuring that therapeutic products imported, sold, distributed and promoted in Tuvalu are safe and effective;

“sell” includes:

- (a) barter; and

- (b) offering or attempting to sell, or having in possession for sale, or exposing for sale, or sending or delivering for sale, or causing or allowing to be sold, or offered or exposed for sale; and
- (c) supplying by way of gift or sample for the purpose of promoting a sale;—

and sale has a corresponding meaning;

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

“supply by wholesale”, in relation to a substance or products, means:

- (a) supply of the substance or products for the purposes of re-supply; or
- (b) supply of an ingredient for the purposes of incorporation in the substance or products;
- (c) supply of the substance or products in wholesale quantities for use-
 - (i) in a public institution; or
 - (ii) in connection with the carrying on by persons, in circumstances required by this Act or the regulations, of any activity so required;

“therapeutic product” means any substance or article, other than a cosmetic, that is manufactured, imported, sold, or supplied wholly or principally for use by one or more human beings or animals for a therapeutic purpose and which includes-

- (a) medicines and products;
- (b) medical devices;
- (c) products for use as an ingredient in the manufacturer of medicinal products and medical devices; and
- (d) products for use as a container or part of a container for products referred to in paragraphs (a) (b) and (c);

“therapeutic purpose” means:

- (a) treating or preventing disease; or
- (b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or
- (c) effecting contraception; or
- (d) inducing anaesthesia; or
- (e) altering the shape, structure, size, or weight of the human body; or
- (f) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and

- whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way; or
- (g) cleaning, soaking, or lubricating contact lenses.

PART II – THE NATIONAL MEDICINES POLICY AND THE NATIONAL DRUGS AND THERAPEUTICS COMMITTEE

5 National Medicine Policy

- (1) The National Drugs and Therapeutics Committee shall develop, and submit to the Minister for approval, a National Medicines Policy.
- (2) The purpose of the Policy is to develop, within the available resources, the potential that therapeutic products have to control diseases and alleviate suffering through promotive, preventative, and curative health services.
- (3) The Policy will contain strategies to help:
 - (a) ensure the long term access and availability of effective and safe essential medicines at an affordable cost;
 - (b) promote the rational, sound, and cost effective use of medicines by health professionals and the public; and
 - (c) sourcing and supply of medicines in disasters and emergencies.

6 Establishment of the Committee

- (1) There shall be established for the purposes of this Act a Committee to be called the National Drugs and Therapeutics Committee.
- (2) The Committee shall consist of:
 - (a) the Director of Health, who shall be the Chair;
 - (b) the Chief Pharmacist; who shall be the Secretary
 - (c) the Medical Superintendent;
 - (d) the Chief Dentist;
 - (e) the Chief Nurse/Matron;
 - (f) the Chief Public Health Officer;
- (3) The Committee can include additional expertise that it may require from time to time in order to effectively carry out its functions.

7 Functions of the Committee

- (1) The functions of the Committee shall be to:

- (a) develop, implement, and periodically review the National Medicines Policy;
- (b) develop and review relevant guidelines, including the Standard Treatment Guidelines, the Guidelines for Donations of Medical Supplies, and the Guidelines for Medical Waste Management;
- (c) develop, maintain, and publish the Tuvalu Medicines Schedule, to list all the medicines or classes of medicines that are approved for use in Tuvalu;
- (d) maintain and publish the Tuvalu Essential Medicines List in accordance with the National Medicines Policy;
- (e) determine the therapeutic products to be purchased by the Ministry of Health based on the Tuvalu Essential Medicines List;
- (f) provide advice to any visiting medical teams, aid or development programmes, or research programmes, where the selection and use of medicines is a significant component;
- (g) provide advice during emergencies and disasters about the need for, selection of, sourcing of, supply of, and use of medicines;
- (h) develop and implement a protocol to guide access to specialist therapeutic products that are not on the Essential Medicines List for individual patients on a case by case basis;
- (i) produce education, guidance and training for health professionals who use therapeutic products;
- (j) undertake the functions of the licensing authority under this Act, including receiving applications for licences under the Act, making decisions on whether to grant or refuse such applications, and to issue licences under the Act;
- (k) receive collate, review and, if necessary, suggest action, upon reports of adverse drug reactions within Tuvalu;
- (l) undertake or approve audits and studies into the use of medicines and develop strategies to ensure the quality of medicines in the supply chain;
- (m) advise the Minister of Health on matters associated with the regulation of therapeutic products; and
- (n) Undertake other functions that are specified in the National Medicines Policy.

8 Procedures of the Committee

- (1) Subject to any requirements under this Act, or regulations, the Committee may regulate its own procedures, proceedings, and rules governing its meetings.

- (2) The Committee shall meet as often as is necessary for the efficient and effective conduct of its functions, and at such times and places as it determines.
- (3) The Committee can form sub-committees to enable it to efficiently and effectively undertake its functions;
- (4) The Committee shall prepare annually a report of its activities during the preceding 12 months and this report shall be made in writing to the Minister.
- (5) Any member of the Committee who has a material conflict of interest concerning a matter before the Committee must declare that conflict and take no part in the Committee's deliberations on that matter.

PART III – SCHEDULING MEDICINES

9 Scheduling of medicines

- (1) The Committee shall maintain a schedule, to be known as the Tuvalu Medicines Schedule, specifying medicines which can be imported into and used in Tuvalu.
- (2) The classes of substances which shall be used for the purpose of the Tuvalu Medicines Schedule shall include:
 - (a) pharmacy only medicines;
 - (b) pharmacist only medicines;
 - (c) prescription medicines;
 - (d) drugs and poisons requiring a caution;
 - (e) poisons;
 - (f) dangerous poisons;
 - (g) dangerous drugs;
 - (h) prohibited substance;
 - (i) unscheduled medicines;
 - (j) any other classes as determined by the Committee.
- (3) In deciding if a given medicine, substance, or class of medicines should be added to the Tuvalu Medicines Schedule, the Committee shall consider the medicine's, substance's or class of medicine's:
 - (a) usefulness to the people of Tuvalu;
 - (b) demonstrated efficacy;
 - (c) safety profile;
 - (d) quality;

- (e) registration or approval status with other recognised medicines regulators.
- (4) The Committee shall annually review the content of the Tuvalu Medicines Schedule and may amend any of the medicines or classes in the Tuvalu Medicines Schedule by notice in the Gazette.
- (5) The Tuvalu Medicines Schedule may be kept in electronic format.
- (6) The Ministry of health shall make the Tuvalu Medicines Schedule readily available to the public and to those wishing to undertake an activity controlled by this Act.

PART IV – CONTROLS ON THERAPEUTIC PRODUCTS

10 Therapeutic products to be approved by a recognised regulator

- (1) Unless authorised by the licensing authority, no person may import, manufacture, sell, supply or promote any therapeutic product unless that product has been approved by a recognised regulator and is on the Tuvalu Medicines Schedule.
- (2) For the purpose of subsection (1) a person who wishes to import, manufacture, sell, supply or promote any therapeutic product person must hold documentation sufficient to satisfy the licensing authority that the product has been approved by a recognised regulator.
- (3) Where a recognised regulator has granted an approval subject to conditions, those conditions apply to supply or promotion of the product in Tuvalu unless those conditions are modified by the licensing authority.
- (4) The giving of an authorisation under subsection (1) shall not render the Crown, the licensing authority, or the Ministry of Health liable to a person in respect of loss, damage or injury of any kind suffered by the person as a result of, or arising out of, the use of therapeutic products by that person or another person.
- (5) Nothing in this section prevents the importation by any person of a medicine when that importation is for personal therapeutic use which is evidenced by a letter or certificate of that person's medical practitioner registered outside Tuvalu or is for the purpose of a clinical trial authorised by regulations made under this Act.
- (6) Any person who contravenes subsection (1) commits an offence punishable by up to one year imprisonment or a fine not exceeding \$10,000.

11 Control of therapeutic products available in Tuvalu

- (1) If the licensing authority has reason to believe that any therapeutic product, may be unsafe or ineffective for the therapeutic purpose for which it is used, it may, by notice in writing to an importer, manufacturer or wholesaler, state the reasons for its belief and require the importer, manufacturer or wholesaler to satisfy the authority of the safety or efficacy of that product.
- (2) If the licensing authority is not satisfied, by evidence supplied of the safety and efficacy of a therapeutic product to which that notice relates, the licensing authority may, by notice in writing to the importer, manufacturer, or wholesaler:
 - (a) prohibit the importer, manufacturer, or wholesale either indefinitely or for such period as may be specified in the notice, from selling or supplying the product in Tuvalu; or
 - (b) impose such conditions as may be specified in the notice on the sale or supply of the product.
- (3) The licensing authority may at any time, by a like notice, revoke any notice given under subsection (2) of this section, or vary, revoke, or add to any conditions imposed in any such notice.
- (4) The licensing authority may order the recall of a therapeutic product by giving notice to an importer, manufacturer or other person supplying the product, where the quality, safety or efficacy of the product becomes unacceptable to the licensing authority; or where the importer or manufacturer or other person supplying the product has failed to comply with a condition to which the Therapeutic Product is subject.
- (5) Every person commits an offence and is liable to a fine not exceeding \$1,000 if they fail to comply with a notice of the licensing authority given under subsection (2).
- (6) Every person commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding \$10,000 who sells or supplies any therapeutic product in contravention of a notice given under subsection (2) of this section, or of a condition imposed in any such notice or in a notice given under subsection (3) or who fails to comply with a notice given under subsection (4).

12 Powers of licensing authority to prohibit import or supply of therapeutic products

- (1) The licensing authority may by notice in the Gazette, prohibit the import, manufacture, packing, sale, possession, supply, administration, or other use of therapeutic products of any specified description, either absolutely or subject to such conditions as the licensing authority thinks fit.

- (2) Where the licensing authority gives a notice under subsection (1) of this section, it shall, on the written request of any person, state its reasons for doing so.
- (3) Every person commits an offence against this Act who contravenes any notice given under subsection (1) of this section and is liable to a fine not exceeding \$10,000.

13 Donated medicines

Donated medicines may only be imported into Tuvalu if they comply with Tuvalu's Guidelines for Donations of Medical Supplies, prepared by the Ministry of Health.

14 Supply of medicines

- (1) Except as may be permitted under this Act or regulations, no person shall, in the course of any business carried on by that person, sell by retail, or supply in circumstances corresponding to retail sale, dispense, or distribute by way of gift or loan or sample or in any other way, any medicine unless:
 - (a) the medicine is a prescription medicine or a pharmacist only medicine:
 - (i) sold, supplied, or dispensed distributed by a pharmacist in a government operated hospital pharmacy or health clinic run or approved by the Ministry of Health, or a pharmacy licensed under this Act; or
 - (ii) supplied by a person who is authorised by the Director of Health to supply and administer any specified class or description of prescription medicine, such as a registered nurse, medical practitioner, or dentist working in a clinic run or approved by the Ministry of Health; or
 - (b) the product is a pharmacy only medicine sold, supplied, or distributed by:
 - (i) a person under the supervision of a pharmacist in a government operated hospital pharmacy or health clinic run or approved by the Ministry of Health, or a pharmacy licensed under this Act; or
 - (ii) a person who sells, supplies, or distributes the medicine in any shop in accordance with a licence issued under this Act
 - (c) the product is a general sales medicine listed in the Tuvalu Medicines Schedule.
- (2) No person may sell, supply, or dispense any prescription medicine otherwise than:
 - (a) under a prescription given by an authorised prescriber; or

- (b) in the case of a registered health professional operating from a government run or approved health clinic, under authorisation by the Director of Health.
- (3) Except as may be permitted by regulations made under this Act, no person shall sell any therapeutic product by means of an automatic vending machine or by auctioning the therapeutic product.
- (4) Except as may be permitted by this Act or by regulations made under this Act, no person shall sell or supply, or offer to sell or supply any prescription, pharmacist only, or pharmacy medicine by way of the internet or other similar form of technology.
- (5) Every person who contravenes subsection (1), (2) (3) or (4) commits an offence and is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding \$10,000.

15 Prescribing, dispensing, and administering prescription medicines

- (1) No person may prescribe a prescription medicine unless they are an authorised prescriber.
- (2) No authorised prescriber shall prescribe any prescription medicine otherwise than for the treatment of a patient under his or her care, unless the prescriber is acting in the course of his employment in the service of the Crown.
- (3) No veterinary surgeon shall prescribe any prescription medicine otherwise than in the practice of his profession for the treatment of an animal under his or her care.
- (4) Except as permitted by regulations made under this Act, no person shall dispense or administer any prescription medicine to any other person otherwise than in accordance with the directions of the authorised prescriber who prescribed the medicine.
- (5) Nothing in subsection (4) prevents a registered nurse from administering a prescription medicine through a hospital or health clinic if they are permitted by the Director of Health, are acting in good faith, and follow the Tuvalu Standard Treatment Guidelines.
- (6) Every person commits an offence against this Act who contravenes subsection (1), (2), and (3) of this section and is liable to a fine not exceeding \$10,000.

16 Labelling of dispensed therapeutic products

- (1) A therapeutic product must be dispensed with the following information clearly and legibly contained on its label:
 - (a) its generic name;
 - (b) the strength of its active ingredient;

- (c) its dose regime;
 - (d) the patients name;
 - (e) the date of dispensing;
 - (f) the quantity of medicine dispensed;
 - (g) any cautionary instructions that are required; and
 - (h) other information required by regulations or specified in the National Medicine Policy.
- (2) Every person commits an offence against this Act who contravenes subsection (1) of this section and is liable on conviction to a fine not exceeding \$10,000.

17 Advertising prohibited

- (1) Except as authorised by regulations made under this Act, and consistent with the National Medicines Policy, no person may publish, or arrange for any other person to publish, any advertisement for a therapeutic product in Tuvalu.
- (2) Every person commits an offence against this Act who contravenes subsection (1) of this section and is liable on conviction to a fine not exceeding \$2,000.

18 Duty to report adverse effects of therapeutic products

- (1) If at any time the importer, manufacturer or supplier of any therapeutic product has reason to believe that any substantial adverse effects have arisen from the use of the therapeutic product whether in Tuvalu or elsewhere, the importer, manufacturer or supplier shall forthwith notify the licensing authority of the nature of those effects and the circumstances in which they have arisen, so far as they are known to that person.
- (2) Every person commits an offence against this Act and is liable to a fine not exceeding \$10,000 who fails to comply with subsection (1) of this section.

19 Restrictions on prescribing and supplying to individuals

- (1) The licensing authority may issue a restriction notice if it has reason to believe that an individual:
- (a) is addicted or habituated to a medicine; and
 - (b) is likely to seek further supplies of, or prescriptions for, that medicine.
- (2) A restriction notice may include:
- (a) exceptions to the restrictions in the notice, including an exception allowing certain specified persons to prescribe or supply the specified medicine to the restricted individual in certain circumstances, specified quantities, or both; and

- (b) any other conditions the licensing authority chooses.
- (3) The licensing authority may revoke or modify a restriction notice by issuing a further notice.
- (4) The licensing authority must serve a copy of a restriction notice or further notice on the restricted individual, but a failure to do so does not invalidate the notice.
- (5) A restriction notice restricts:
 - (a) prescribers from prescribing the medicine specified in the notice to the restricted individual named in the notice; and
 - (b) persons from supplying the medicine specified in the notice to the restricted individual named in the notice.

20 Prescribing or supplying in contravention of restriction notice

- (1) A person must not prescribe or supply medicines to a restricted individual in contravention of a restriction notice.
- (2) Every person who knows, or who ought reasonably to have known, that the person prescribed or supplied medicines is a restricted individual commits an offence and is liable, on conviction:
 - (a) in the case of an individual, to a term of imprisonment not exceeding 3 months, or a fine not exceeding \$10,000, or both; and
 - (b) in the case of a body corporate, to a fine not exceeding \$10,000.

PART V – LICENSING

21 Licences required

- (1) Unless they have a valid licence permitting them to do so, issued under this Act, no person shall, in the course of any business carried on by that person:
 - (a) import any therapeutic product; or
 - (b) manufacture any therapeutic product; or
 - (c) sell any therapeutic product by wholesale; or
 - (d) pack or label any therapeutic product; or
 - (e) sell any therapeutic product by retail; or
 - (f) operate any pharmacy or carry on the practice of pharmacy at any premises;
- (2) Subsection (1) does not apply to such activities undertaken by hospitals or health clinics operated or approved by the Ministry of Health.

- (3) Every person who contravenes subsection (1) commits an offence and is liable on conviction to a fine not exceeding \$10,000.
- (4) 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 punishable by a fine not exceeding \$10,000.

22 Register of licences

- (1) The licensing authority shall keep, and maintain up to date, a register of the licences it has issued under this Act in a form that it thinks fit.

23 Application for licences

- (1) Every application for a licence must be made to the licensing authority in the form required by the licensing authority.
- (2) Applications under this Part shall contain or be accompanied by such particulars, information, documents, samples, plans or specifications, and other material as may be required by the licensing authority, and shall be accompanied by a prescribed fee.
- (3) The licensing authority may require an applicant for a licence to supply such information additional to that contained in the application as it thinks fit.

24 Granting licences

- (1) The licensing authority must not grant a licence under this Act unless, on receiving an application, the licensing authority is satisfied of all the following matters:
 - (a) That the requirements of section 21 of this Act have been complied with;
 - (b) That, in the case of an application made by a natural person on his or her own behalf, the applicant is a fit and proper person to hold the licence applied for, or, in the case of an application made on behalf of a body corporate, the applicant (body corporate) is controlled by fit and proper persons;
 - (c) That, in the case of an application made by a natural person on their own behalf, the applicant, or, in the case of an application made on behalf of a body corporate, every person proposed to be a responsible person for the purposes of the licence applied for, has a sufficient knowledge of the obligations of a licensee under the Act and of the hazards associated with the therapeutic products in which it is proposed to deal;

- (d) That the premises and equipment that the applicant proposes to use are suitable and adequate for the purposes for which the licence is sought;
 - (e) That adequate arrangements have been made or are to be made for the making, maintaining, and safekeeping of adequate records in respect of therapeutic products and activities permitted under the licence.
- (2) The licensing authority shall not decline an application for a licence under this section without first giving the applicant a reasonable opportunity to be heard.
 - (3) The licensing authority can grant a licence subject to any conditions it thinks fit.
 - (4) All licences granted shall be issued in a form determined by the licensing authority.

25 Mandatory conditions of licence to operate pharmacy

- (1) It is a condition of every licence to operate a pharmacy that:
 - (a) Every pharmacy must be operated under the supervision and control of a pharmacist; and
 - (b) No prescription medicine, or other class of therapeutic product prescribed in the regulations, may be dispensed or supplied by a person other than a pharmacist; and
 - (c) the holder of the licence must not request or require any pharmacist who is employed or engaged in duties at a pharmacy to act in a way that is inconsistent with the applicable professional or ethical standards of pharmacy practice; and
 - (d) Every person who operates a pharmacy must ensure that every prescription medicine or restricted medicine in the pharmacy is at all times secured in a way that prevents the public gaining ready access to the medicine.
- (2) Subsections (1)(a) to (d) do not prevent a pharmacist engaged at the pharmacy or another person authorised by a pharmacist engaged at the pharmacy, from supplying any medicine to a member of the public.
- (3) The requirements imposed by subsection (1)(c) and (d) are in addition to the conditions imposed by any licence granted under this Act.

26 Term and renewal of licences

- (1) Every licence, unless sooner suspended or cancelled under this Act, continues in force for a period of 1 year and then expires.
- (2) Each licensee must apply to the licensing authority (in the form and manner required by the licensing authority) to renew their licence if they wish to continue to be licensed after the expiry of the term of their current licence.

27 Display of licences

- (1) Every licensee shall cause their current licence to be permanently exhibited in some conspicuous place where it can be readily seen by all persons having access to the premises to which the licence relates.
- (2) Every licensee shall produce their licence for inspection whenever required by an authorised officer to do so, or, if he is unable to do so, shall produce it at the office of the licensing authority within 24 hours thereafter.
- (3) 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. This subsection does not apply to any hospital pharmacy operated by the Ministry of Health.
- (4) Every person commits an offence who contravenes subsection (1), or fails to produce their licence as required by subsection (2), of this section, punishable by a fine not exceeding \$1,000.

28 Suspension or cancellation of licences

- (1) If the licensing authority is satisfied that the holder of a licence has failed or is failing to comply with any conditions of the licence, it may:
 - (a) suspend the licence for such reasonable period as may be required to enable the licensing authority to consider the case; or
 - (b) after giving the licensee a reasonable opportunity to be heard and considering any evidence adduced or submission made by the licensee, cancel the licence.
- (2) The licensing authority may suspend or cancel 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.
- (3) Before suspending or cancelling the licence, the licensing authority 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 licence should not be suspended or cancelled.
- (4) If no cause is shown within the time stipulated in the notice referred to in subsection (3), or if cause is shown but the licensing authority is not satisfied with it, the licensing authority may suspend or cancel the licence.
- (5) The order of the licensing authority under subsection (3) takes effect from such date as is specified in the order.

29 Standards of pharmacy premises

- (1) The standards for pharmacy premises shall be prescribed by the licensing authority.
- (2) A person carrying on the practice of pharmacy shall keep any documents required by the licensing authority on the premises.
- (3) The requirements imposed by subsections (1) and (2) are in addition to the requirements imposed by any regulations made under this Act.
- (4) Any person who, without reasonable excuse, fails to keep the publications required under this section commits an offence punishable by a fine not exceeding \$8,000.

PART VI – MONITORING AND ENFORCEMENT**30 Authorised officers**

- (1) The Director of Health may appoint a person or persons as authorised officers for the purposes of this Act. The Director may appoint:
 - (a) registered pharmacists;
 - (b) registered nurses;
 - (c) other registered health professionals;
 - (d) any other person the Director considers qualified to act as an authorised officer.
- (2) The Director may at any time, entirely at his or her discretion, revoke the appointment of any authorised officer.
- (3) When exercising his or her powers under this Act, an authorised officer appointed under subsection (1) is subject to any directions given by the Director.
- (4) The Director shall supply every authorised officer with a warrant of designation that shall both provide evidence of the identity of that person and of the designation of that person as an authorised officer under this Act.

31 Powers of entry, search and 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 therapeutic products are being dealt with under a licence issued under this Act;

- (c) enter any place, premises or vehicle in respect of which he or she knows or reasonably suspects:
 - (i) is or are being used in the course of business associated with therapeutic products; or
 - (ii) is or are being used for the practice of pharmacy; or
 - (iii) have been or are being or are likely to be used by any person acting in contravention of this Act;
 - (d) enter any premises where he knows or reasonably suspects that records are kept which may provide evidence relating to a contravention of this Act;
 - (e) in any premises entered:
 - (i) search for or examine therapeutic products, articles, equipment or documents, take possession of any therapeutic products, articles, equipment or documents, or samples thereof, or make copies of or extracts from records relating to any matter relevant to an investigation under this Act;
 - (ii) seize any therapeutic products, articles, equipment, documents, or samples thereof, or container or package which he reasonably suspects to contain any therapeutic products, articles or equipment;
 - (iii) open any room, place, container or package that he knows or reasonably suspects contains any documents, therapeutic products, articles or equipment;
 - (iv) question with respect to matters under this Act any person he finds thereon;
 - (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 Resident Magistrate.
- (4) A Resident Magistrate, if satisfied upon the information of an authorised officer that there is reasonable cause to suspect that any place has been, or is being, or is likely to be used in connection with 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, shall 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.

32 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 their possession or under their control in any place, whether for their 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 thereof 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 refuse or fail to furnish any information, records or copy as required under this section nor 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 punishable by a fine not exceeding \$5,000.

33 Continuing offence

If a person commits an offence by failing to furnish information required under section 32 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 not exceeding \$100 for each day during which the offence continues; and

- (d) the person may be prosecuted from time to time in respect of the offence under subsection (b) above.

34 Obstruction

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

35 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 in every respect 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 punishable by a fine not exceeding \$5,000.

36 Making false or fraudulent representation

A person who for the purpose of any application 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 to a fine not exceeding \$5,000 or to imprisonment for a term not exceeding 12 months or both.

37 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.

38 Prosecutions

- (1) Prosecutions for an offence under this Act may be brought:
 - (a) by or on behalf of the Attorney General; or
 - (b) by a member of the police; or
 - (c) by an authorised officer; or
 - (d) by a customs officer.
- (2) A person referred to in subsection (1)(b), (c) or (d), 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.

39 Protection of authorised officers

- (1) An authorised officer shall not be personally liable in respect of any act done in the execution or purported execution of the officers duties under this Act and within the scope of the officer's employment if it was done in the honest belief that his or her duties under this Act required or entitled him or her to do it.
- (2) Nothing in this section shall be construed as relieving the Department from any liability in respect of acts of its officers in the course of their employment.

PART VII – MISCELLANEOUS PROVISIONS

40 Contracts inconsistent with this Act

- (1) A contract, agreement, undertaking or understanding that 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).

41 Application of the Customs Act 1963

Any therapeutic product which does not comply with this Act or the regulations is deemed to be a prohibited good under the Customs Act 1963.

42 Relationship with the Dangerous Drugs Act 1948

If a therapeutic product is also a dangerous drug under the Dangerous Drugs Act 1948, the prohibitions, conditions, and requirements in this Act are in addition to those contained in or imposed under the Dangerous drugs Act 1948.

43 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.

44 Automatic vending machines prohibited

Any person who:

- (a) installs any automatic machine for the sale or supply of any therapeutic product 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 therapeutic product by any automatic machine; or
- (c) allows or permits any person to purchase or be supplied with or otherwise obtain any therapeutic product by any automatic machine;

commits an offence punishable by a fine not exceeding \$10,000.

45 Regulations

- (1) The Minister may, with the consent of the Cabinet, make regulations that are required to give full effect to the purposes or provisions of this Act.
- (2) Regulations may be made under this section for such purposes, including:
 - (a) prescribing the fees payable under this Act and the regulations;

- (b) exempting from the operation of any of the provisions of this Act or the regulations such persons or classes of persons as may be specified;
- (c) specifying descriptions and classifications for substances, including those to be used in the Tuvalu Medicines Schedule or Tuvalu Essential Medicines List;
- (d) controlling or restricting activities related to any substances or class of substance on the Tuvalu Medicines Schedules;
- (e) regulating any procedure for developing, maintaining, publishing, or revising the Tuvalu Medicines Schedule or Tuvalu Essential Medicines List;
- (f) prescribing forms, fees, registers, lists, particulars, notifications, and records for the purposes of this Act, the method of keeping such registers, lists, and records, and the manner of making applications under this Act; and prescribing the persons or classes of persons by or to whom any such records shall be kept or notifications given;
- (g) prescribing qualifications for and conditions of licences under this Act; and providing for or regulating the application for and granting of, display, custody of, production, suspension, or revocation of such licences;
- (h) permitting activities otherwise than pursuant to a licence under this Act and otherwise than in accordance with an authority conferred by this Act, subject to such conditions or restrictions (if any) as may be prescribed by or imposed under the regulations;
- (i) prohibiting, limiting, restricting, or imposing conditions on, either generally or in relation to particular cases or classes of case, or particular descriptions or classes of therapeutic products, or particular classes of person, the import, export, possession, prescribing, dispensing, compounding, manufacture, packing, labelling, storage, safekeeping, administration, destruction, disposal, sale, or supply of therapeutic products;
- (j) regulating the manufacture, compounding, dispensing, packing, labelling, storage, safe-keeping, and destruction of therapeutic products in pharmacies;
- (k) regulating the operation of pharmacies, including setting standards, requirements to be met;
- (l) prescribing and regulating the mode of labelling of packages and containers of therapeutic products supplied by a pharmacy;
- (m) withdrawing therapeutic products from sale;
- (n) specifying, by name or description, kinds or classes of products that shall be deemed not to be therapeutic products for the purposes of this Act;

- (o) prescribing and regulating the mode of labelling of packages and containers;
- (p) prohibiting the use of any package or container of a kind specified or described in the regulations for any purpose other than the storage of medicines for internal use;
- (q) authorising any class of registered health professional to prescribe prescription medicines of a specified class or description in accordance with such conditions, limitations, requirements, or restrictions specified in or imposed under the regulations;
- (r) regulating the issue of standing orders, imposing conditions, limitations, requirements, or restrictions in relation to the contents of standing orders and their use, and providing for such other matters as are necessary or desirable for the administration of standing orders;
- (s) regulating the procedure of any committee established under this Act;
- (t) prescribing offences in respect of the contravention of or non-compliance with any regulations made under this Act, and the amounts of fines that may be imposed in respect of any such offences, which fines shall be an amount not exceeding \$8,000 and, where the offence is a continuing one, a further amount not exceeding \$100 for every day or part of a day during which the offence has continued;
- (u) exempting, or providing for the exemption of, any persons or classes of persons, or excepting any description or class of therapeutic products, from any provision of any regulation made under this Act that imposes conditions or obligations;
- (v) prohibiting or regulating the advertising of therapeutic products;
- (w) prohibiting or regulating the performance of clinical trials in Tuvalu;
- (x) prohibiting the importation, sale, supply, promotion or the performance of any other activity associated with a therapeutic product or class of products;
- (y) regulating the storage, security, or disposal of therapeutic products; and
- (z) prescribing any other matter necessary for the due administration of this Act and for giving full effect to the Act.

46 Savings and transitional provisions

- (1) All persons who, at the commencement of this Act, were licensed under the Pharmacy and Poisons Act 1948, shall be deemed to be licensed under this Act.
- (2) Any application for a licence under the Pharmacy and Poisons Act 1948 that was pending immediately before the commencement of this Act must be considered and dealt with under this Act.

47 Repeals

The Pharmacy and Poisons Act 1948 is repealed.

48 Consequential amendments

If this Bill is passed, a number of consequential amendments will be needed. This will include having to repeal references to the Pharmacy and Poisons Act 1948 in the following legislation:

- (a) The Dangerous Drugs Act (sections 15(2), 15(3))

NB: if the Health Professionals Bill developed in 2011 is passed by Parliament then references to the Pharmacy and Poisons Act 1948 in other legislation will also have to be replaced with Health Professionals Bill developed in 2011.

48 Regulations revoked

The Pharmacy and Poisons Regulations 1954 are revoked.