

**GOVERNMENT OF FIJI**

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**MEDICINAL PRODUCTS DECREE 2011**  
**(Decree No.    of 2011)**

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IN exercise of the powers vested in me as President of the Republic of Fiji and the Commander in Chief of the Republic of Fiji Military Forces by virtue of the Executive Authority of Fiji Decree 2009, I hereby make the following Decree —

**TO PROTECT THE HEALTH AND SAFETY OF THE PUBLIC BY REGULATING  
MEDICINAL PRODUCTS, DEVICES, POISONS AND SIMILAR PRODUCTS IN  
ACCORDANCE WITH THE NATIONAL MEDICINAL PRODUCTS POLICY AND TO  
PROVIDE FOR THE REGULATION OF THE IMPORT, MANUFACTURE, EXPORT, SUPPLY,  
SALE, ADVERTISING AND PROMOTION OF MEDICINAL PRODUCTS, DEVICES AND  
POISONS WHICH ARE OF ACCEPTABLE QUALITY, SAFETY AND EFFICACY.**

PART 1 - PRELIMINARY

*Short title and commencement*

1. - (1) This Decree may be cited as the Medicinal Products Decree 2011.

(2) This Decree shall come into force on a date appointed by the Minister by notice in the *Gazette*.

*Objects*

2. - (1) The object of this Decree is to protect the health and safety of the public by regulating medicinal products, devices, poisons and similar products in accordance with the National Medicinal Products Policy.

(2) This Decree provides for regulation of the import, manufacture, export, supply, sale, advertising and promotion of medicinal products, devices and poisons which are of acceptable quality, safety and efficacy.

*Interpretation*

3. In this Decree, unless the context otherwise requires-

"adulterated" means the addition of any substance to or subtraction of any constituent from a drug or device so as to affect its quality composition or potency;

"advertisement" includes any representation by any means whatsoever, for the purpose of promoting directly or indirectly, the manufacture, sale or disposal of any drug or device;

"appointed dangerous drugs store" means the store for dangerous drugs designated in the Regulations made under this Decree;

"approved" in relation to a form, procedure or other matter means approved by the Board;

"Board" means the Fiji Medicinal Products Board established under Part 2;

"Chief Pharmacist" means the public service employee appointed to or acting in the position of Chief Pharmacist in the Ministry of Health;

"clinical trial" means a systematic study on any medicine in human subjects including patients and volunteers in order to-

- (a) discover or verify the effects of, or identify any adverse reaction to the medicine that is being investigated; or
- (b) study the absorption, distribution, metabolism and excretion of the medicine with the objective of ascertaining the safety or efficacy of the medicine;

"code of conduct" means a code of conduct issued by the Board;

"committee" means a committee of the Board;

"compound" in relation to a medicine or a poison means a medicine or a poison prepared in accordance with a formula and being a combination of medicines or poisons compounded in such a way that one or more constituents cannot be readily separated from the other substance or substances and to compound and derivative expressions have corresponding meanings;

"Comptroller" means the Comptroller of Customs and Excise;

"condition" includes limitation or restriction;

"conditional registration" means entry in the appropriate register subject to conditions set by the Board;

"Convention" means any international convention relating to the control in the manufacture of and traffic in drugs to which Fiji is or becomes a party;

"controlled poison" means a substance listed in the Regulations enacted under this Decree;

"conveyance" means ship, motor vehicle, aircraft, train and any other means of transport by which goods may be brought into or taken from Fiji;

"counterfeit medicine" means a medicine in respect of which-

- (a) the label or presentation of the medicine;
- (b) any document or record relating to the medicine or its manufacture; or
- (c) any advertisement for the medicine,

contains a false representation of any one of the following-

- (i) identity or name of the medicine;
- (ii) formulation, composition or design specification of the medicine or of any ingredient or component of it;
- (iii) presence or absence of any ingredient or component of the medicine;
- (iv) strength or size of the medicines, other than the size of any pack in which the medicine is contained;
- (v) strength or size of any ingredient or component of the medicine; or
- (vi) sponsor, source, manufacturer or place of manufacture of the medicine;

"dangerous drug" means a substance listed in the Regulations enacted under this Decree;

"dangerous poison" means a substance listed in the Regulations enacted under this Decree;

"dentist" means a person for the time being registered under the Medical and Dental Practitioner Decree 2010;

"device" means a product consisting of an instrument, apparatus, appliance, material or other product, 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 although it may be assisted in its function by such means, but does not include a-

- (a) medicinal product; or
- (b) product declared not to be a device by the Minister by Regulations enacted under this Decree;

"export authorisation" means an authorisation issued by a competent authority in a country from which a dangerous drug is exported-

- (a) containing-
  - (i) full particulars of the drug and the quantity authorised to be exported; and
  - (ii) the names and addresses of the exporter and the person to whom it is to be sent; and
- (b) stating the country to which and the period within which it is to be exported;

"Fiji Medical Council" means the Council referred to in section 4 of the Medical and Dental Practitioner Decree 2010;

"financial year" means the period from 1<sup>st</sup> April to 31<sup>st</sup> March of the following year;

"general exemptions list" means the list in the Regulations enacted under this Decree;

"general sale medicine" means a substance or class of substance listed in the Regulations enacted under this Decree;

"Government Analyst" means the person for the time being holding the office of the Government Analyst and includes any additional Government Analyst, Deputy Government Analyst, Senior Assistant Government Analyst or Assistant Government Analyst;

"hazardous poison" means a substance listed in the Regulations enacted under this Decree;

"health services" means-

- (a) medical or dental services;
- (b) physiotherapy, psychology, podiatric, occupational therapy, acupuncture, chiropractic, chiropody or osteopathy services; or
- (c) any other service declared by the Minister, by notice in the *Gazette*, to be a health service for the purposes of this Decree;

"health services permit" means a permit authorising a person to purchase, import or otherwise obtain and use medicines for the provision of health services;

"import" means to bring or cause to be brought into Fiji by sea or air;

"import authorisation" means an authorisation issued by a competent authority authorising the importation of a specified quantity of a dangerous drug-

(a) containing-

- (i) full particulars of the drug;
- (ii) the name and address of the person authorised to import the drug; and
- (iii) the name and address of the person from whom the drug is to be obtained; and

(b) specifying the time within which the importation must be effected;

"import certificate" means a certificate issued by a competent authority in a country from which it is intended to import a dangerous drug;

"insanitary conditions" means such conditions or circumstances as are likely to contaminate a product;

"in transit" means taken or sent from any country and brought into Fiji by land, air or water, whether or not landed or trans-shipped in Fiji, for the sole purpose of being carried to another country either by the same conveyance or another conveyance;

"label" includes any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on or attached to a container of a drug or device;

"labelling" includes the label and any written, printed or graphic matter relating to and accompanying the drug or device;

"manufacture" includes the process of refining, manipulating and mixing a medicine or poison, including a medicine or poison in a raw state, but does not include the process that is carried out by a pharmacist in the lawful practice of his or her profession in-

(a) premises used for supply or sale by retail; or

(b) a hospital pharmacy department in which the pharmacist manufactures preparations of medicines and poisons for supply or sale or distribution only from those premises or from such other premises as may be owned and operated by that pharmacist selling or supplying by retail;

"manufacturer" means a person who manufactures medicine or poison;

"manufacturing licence" means, in relation to a-

(a) medicine, a licence granted, authorising the carrying out of manufacturing and selling or supplying of medicines, whether by wholesale or retail; or

(b) poison, a licence granted, authorising the carrying out of manufacturing and selling or supplying of poisons, whether by wholesale or retail;

"medicinal product" means a substance or product, not being an instrument, apparatus or appliance that is represented to achieve, or likely to achieve, its principal intended action by

pharmacological, chemical, immunological or metabolic means in or on the body of a human or an animal and that is-

(a) represented in any way to be, or that is, whether because of the way that it is presented or for any other reason, likely to be taken to be for-

- (i) therapeutic use;
- (ii) use as an ingredient or component in the manufacture of medicines;
- (iii) use as a container or part of a container for medicines of a kind referred to in subparagraph (i) or (ii); or

(b) included in a class of substances or products, the sole or principal use of which is or ordinarily is a-

- (i) therapeutic use; or
- (ii) use of a kind referred to in paragraph (a) (ii) or (iii) and includes substances and products declared to be medicinal products under this Decree, but does not include-

(A) substances or products declared under this Decree or Regulations-

- (i) not to be medicinal products; or
- (ii) not to be medicinal products when used, advertised or presented for supply in a specified way if the substances or products are used, advertised or presented for supply in that way;

(B) food;

(C) any herbal drug or herbal medicine or a homoeopathic drug or homeopathic medicine; or

(D) prohibited substances;

"Minister" means the Minister of Health;

"Ministry" means the Ministry of Health;

"package" includes anything in which any drug or device is wholly or partly contained, placed or packed;

"Permanent Secretary" means the Permanent Secretary in the Ministry;

"pharmacist only medicine" means a substance listed in the Regulations enacted under this Decree;

"pharmacy" means premises in or from which a registered pharmacist supplies, compounds or dispenses medicines to the public and includes the portion of the premises where the pharmacist sells or offers to sell goods of any kind;

"pharmacy only medicine" means a substance listed in the Regulations enacted under this Decree;

"pharmacy services" includes-

- (a) supplying, compounding or dispensing of medicines; and
- (b) advising and counselling on the effective and safe use of medicines;

"poison" means a substance listed in the Regulations enacted under this Decree;

"prescribed" means prescribed by this Decree or by the Regulations;

"prescription only medicine" means a substance listed in the Regulations enacted under this Decree;

"principal investigator" in relation to a clinical trial, means the person who is in charge of the conduct of the clinical trial;

"product information" in relation to a proprietary medicine, means information relating to the safe and effective use of the proprietary medicine, including information regarding the usefulness and limitations of the proprietary medicine;

"products" includes medicinal products, devices, poisons, substances and preparations covered under a convention;

"prohibited substance" means a substance listed in the Regulations enacted under this Decree;

"prohibited substance permit" means a permit granted authorising a person to purchase, import or otherwise obtain and to possess and use a prohibited substance for industrial, educational, advisory or research purposes;

"proprietary medicine" means a medicine other than a medicine or a class of medicine that is-

- (a) exempted by the Regulations;
- (b) exempted under the Decree; or
- (c) extemporaneously dispensed or prepared for a specific and individual case;

"Provisionally Authorised Devices Register" means the register established under the Decree to register medicinal devices in respect of which a notification has been received on or before the appointed date published in the *Gazette* for the commencement of the registration of devices;

"Provisionally Authorised Medicinal Products Register" means the register established under the Decree to register medicinal products in respect of which a notification has been received on or before the appointed date published in the *Gazette* for the commencement of the registration of medicinal products;

"Provisionally Authorised Poisons Register" means the register established under the Decree to register poisons in respect of which a notification has been received on or before the appointed date published in the *Gazette* for the commencement of the registration of poisons;

"Provisionally Authorised Products Register" means the register established under the Decree to register any other products in respect of which a notification has been received on or before the appointed date published in the *Gazette* for the commencement of the registration of any other products (referred to as a specified product);

"record" means-

- (a) a documentary record;
- (b) a record made by an electronic, electromagnetic, photographic or optical process; or
- (c) any other kind of record;

"Registered Devices Register" means the register established under the Decree to register devices;

"Registered Medicinal Products Register" means the register established under the Decree to register medicinal products;

"Registered Poisons Register" means the register established under the Decree to register poisons;

"Registered Products Register" means the register established under the Decree to register any other product (referred to as a specified product);

"Registrar" means the Chief Pharmacist serving as the head of the Fiji Medicinal Products Board Secretariat;

"Secretariat" means the Fiji Medicinal Products Board Secretariat established by Part 4;

"sell" means sell whether by-

- (a) wholesale or retail or otherwise, barter, exchange, deal in, agree to sell, offer or expose for sale, keep or have in possession for sale, send forward, deliver or receive for, or for the purpose of sale or in the course of sale; or
- (b) authorising, directing, allowing, causing, suffering, permitting or attempting any of the acts or things mentioned in paragraph (a) and "sale" and the derivatives of "sell" have corresponding meanings;

"sponsor" means-

- (a) a manufacturer, importer, wholesale dealer or other person who, in Fiji, is primarily responsible for placing a proprietary medicine on the market in Fiji; or
- (b) in respect of a proprietary medicine that is placed on the market in Fiji by two or more manufacturers, importers, wholesale dealers or other persons independently, includes each of those importers, wholesale dealers or other persons;

"substance" includes material, preparation, extract and admixture;

"supply" means-

- (a) supply, provide, give or deliver, whether or not for fee, reward or consideration or in expectation of fee, reward or consideration;
- (b) agree or offer for the purpose of supply as defined in paragraph (a), expose for the purpose of supply as so defined, keep or have in possession for the purpose of supply as so defined, send forward or receive for the purpose of supply as so defined; or
- (c) authorise, direct, cause, allow, suffer, permit or attempt to do any of the acts or things referred to in paragraphs (a) or (b) and derivatives of supply have corresponding meanings;

"therapeutic use" means use in or in connection with-

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

"vending machine" means a machine or mechanical device used or capable of being used for the purpose of supplying goods without the personal manipulation or attention of the seller or supplier or an employee or other agent of the seller or supplier at the time of the sale or supply;

"veterinary surgeon" means a person for the time being registered under the Veterinary Surgeons Act (Cap. 257);

"WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce" means the certification scheme on the quality of pharmaceutical products moving in international commerce adopted by the World Health Organization and any amendments to that scheme;

"wholesale" means sale or supply-

- (a) for the purpose of resale;
- (b) to a person for the purposes of supply by that person to another person; or
- (c) for the purposes of use in connection with a trade, business, profession or industry.

## PART 2 - THE FIJI MEDICINAL PRODUCTS BOARD

### *Establishment of the Fiji Medicinal Products Board*

4. - (1) This section establishes the Fiji Medicinal Products Board as a corporate body, with perpetual succession and a common seal.

(2) The Board-

- (a) may sue and be sued in its corporate name;
- (b) has all the powers of a natural person that are capable of being exercised by a corporate body; and
- (c) has the functions and powers conferred by or under this Decree.

(3) If a document appears to bear the common seal of the Board, it is presumed, in the absence of proof to the contrary, that the common seal of the Board was duly affixed to the document.

### *Composition of the Board*

5. - (1) The Board shall consist of 12 members appointed by the Minister.

(2) In appointing the members of the Board, the Minister shall ensure that they comprise of the following-

- (a) Permanent Secretary for Health who shall be the Chairperson;
- (b) Chief Pharmacist who shall be the Deputy Chairperson;

- (c) Government Analyst or his or her nominee;
- (d) two persons who shall be registered pharmacists and who shall be nominated by the Fiji Pharmaceutical Society, one of whom with experience in retail pharmacy services and the other with experience in the private sector;
- (e) two persons who shall be representatives of the School of Medicine with qualifications or experience in pharmacology and who shall be nominated by the Dean of the College of Medicine, Nursing & Health Sciences, of the Fiji National University;
- (f) one person who shall be a representative of the Fiji Medical Association;
- (g) one person who shall be a representative of the Fiji College of General Practitioners; and
- (h) three persons with an interest in medicine, law, pharmaceutical industry or consumer affairs.

*Powers of the Board*

6. - (1) The Board has power to do all things necessary or convenient to be done for, or in connection with the performance of its functions under this Decree.

(2) Without limiting subsection (1), the Board has the power to-

- (a) do all things that a corporate body can do, consistent with its functions under this Decree;
- (b) require medicinal products, poisons and devices manufactured in, imported into and exported from Fiji to conform to prescribed standards of quality, safety and efficacy and that the personnel, premises and practices employed to manufacture, procure, store, promote, distribute and sell such products conform to specified requirements and applicable codes of conduct and good practices;
- (c) require continued conformity of medicinal products, poisons and devices with the applicable standards and requirements until their delivery to the end-user;
- (d) require that medicinal products, poisons and devices are imported, manufactured, exported, stocked, sold, distributed or otherwise dealt with by duly authorised persons or persons working under their supervision;
- (e) grant authorisation or licences for medicinal products, poisons and devices;
- (f) suspend or cancel the authorisation or licence of medicinal products, poisons and devices and recall from the market, medicinal products, poisons and devices whereby the continued use may be detrimental to health;
- (g) inspect and license manufacturing premises and the premises of importers, wholesalers, distributors and retail outlets where medicinal products, poisons and devices are stored;
- (h) monitor the medicinal products, poisons and devices marketed or available for marketing;
- (i) take samples for testing and ensure compliance with applicable standards and requirements;
- (j) ensure that the promotion and marketing of medicinal products, poisons and devices are in accordance with applicable requirements and codes;
- (k) approve the use of unregistered or unauthorised medicinal products, poisons and devices for purposes of clinical trials or for compassionate use and to regulate such trials and such use;
- (l) regulate the dissemination of information on medicinal products, poisons and devices;
- (m) formulate standards and issue codes of practice and professional standards for persons dealing with medicinal products, poisons and devices;
- (n) advise the Minister on the implementation of the law and the need for changes; and
- (o) delegate its functions consistently with the power of delegation.

*Functions of the Board*

7. - (1) The functions of the Board are to-

- (a) grant authorisation or licences for medicinal products, poisons and devices;

- (b) grant licences for manufacturing premises and the premises of importers, wholesalers, distributors and retail outlets where medicinal products, poisons and devices are stored;
- (c) formulate standards and prepare or endorse codes of practice;
- (d) ensure that medicinal products, poisons and devices of acceptable quality, safety, efficacy and reasonable price are available;
- (e) provide advice to the Minister as the Board considers appropriate or as the Minister requests; and
- (f) carry out other functions assigned to the Board by or under this Decree or by the Minister in writing.

(2) The Board must perform its functions under this Decree by achieving and maintaining high professional standards both of competence and conduct in the provision of services relating to medicinal products, poisons and devices in Fiji.

### PART 3 - PROCEEDINGS OF THE FIJI MEDICINAL PRODUCTS BOARD

#### *Terms and conditions of membership*

8. - (1) The Chairperson and members of the Board shall hold office for 3 years, and are eligible for re-appointment.

(2) The Minister may remove a member of the Board from office, if the member-

- (a) conducts himself or herself in a manner that brings the profession into disrepute;
- (b) is absent from 3 consecutive meetings of the Board without reasonable excuse; or
- (c) fails to carry out or becomes incapable of performing satisfactorily the duties of a Board member.

(3) A member is taken to have vacated office if the member-

- (a) dies;
- (b) completes a term of office and is not reappointed;
- (c) resigns by written notice to the Minister;
- (d) ceases to satisfy the qualification by virtue of which the member was eligible for appointment to the Board; or
- (e) is removed from office under subsection (2).

(4) In the event of a vacancy and another person is appointed for such vacancy, such persons shall hold office for the remaining of the term of his or her predecessor.

#### *Vacancies or defects in appointment of members*

9. A decision, action or proceeding of the Board is not invalid by reason only of a vacancy in its membership or a defect in the appointment of a member.

#### *Procedure*

10. - (1) Every meeting of a Board shall be chaired by the presiding member or in that member's absence, by the deputy presiding member. In the absence of both the presiding member and the deputy presiding member, members present may for that particular meeting choose a member to preside at the meeting.

(2) A decision by a majority of the votes cast by members of the Board at a meeting, is a decision of the Board.

(3) Each member present at a meeting of the Board has one vote on any question arising for decision and the member presiding at the meeting may exercise a casting vote if the votes are equal.

(4) In the absence of the Chairperson from any meeting of the Board, the Deputy Chairperson shall, for the purposes of such meeting, act as the Chairperson exercising all the powers of the Chairperson.

(5) At any Board meeting, the quorum shall be the Chairperson, or in his or her absence, the Deputy Chairperson and four members.

(6) If the Chairperson and Deputy Chairperson are both absent from a Board meeting then the meeting is to be cancelled.

(7) The Board may hold meetings, or allow members to take part in meetings by using any technology allowing reasonably contemporaneous and continuous communication between members taking part in the meeting.

(8) A member who takes part in a Board meeting under subsection (7) is taken to be present.

(9) Accurate minutes of every Board meeting must be kept.

(10) The Minister may-

- (a) direct the Board to change its procedures or to adopt new procedures, if the Minister considers it necessary to achieve efficient and accountable operation of the business of the Board; and
- (b) not give a direction that has the effect of overruling a decision of the Board on a professional matter.

#### *Delegation*

11. - (1) The Board may delegate any of its functions or powers under this Decree other than this power of delegation.

(2) A delegation-

(a) may be made to a-

- (i) member of the Board, the Registrar or an employee of the Secretariat; or
- (ii) committee established by the Board,

(b) may be made subject to conditions and limitations specified in the instrument of delegation; and

(c) is revocable at will and does not derogate from the power of the Board to act in a matter.

#### *Conflict of interest*

12. A member of the Board is not taken to have a direct or indirect interest in a matter, by reason only of the fact that the member has an interest in the matter that is shared in common with persons, with a similar professional or occupational background generally or a substantial section of persons registered under the Medical and Dental Practitioner Decree 2010 and Pharmacy Profession Decree 2011.

#### *Powers of the Board in relation to witnesses, etc*

13. - (1) For the purposes of proceedings before the Board, the Board may-

- (a) by summons signed on behalf of the Board by a member of the Board or the Registrar, require the attendance before the Board of any person whom the Board thinks fit to call before it;
- (b) by summons signed on behalf of the Board by a member of the Board or the Registrar, require the production of any relevant documents, records or equipment and in the case of a document or record that is not in the English language, require the production of a-
  - (i) written translation of the document or record into English; and
  - (ii) certificate signed by a translator approved by the Board certifying that the translation accurately reproduces in English the contents of the document or record;
- (c) investigate any documents, records or equipment produced before it, and retain them for such reasonable period as it thinks fit and make copies of the documents or records or their contents;
- (d) require any person to make an oath or affirmation (which may be administered by any member of the Board) to answer truthfully questions put by any member of the Board or any person appearing before the Board; or
- (e) require any person appearing before the Board (whether summoned to appear or not) to answer any questions put by any member of the Board or by any person appearing before the Board.

(2) On the receipt of an application for the issue of a summons under this section, a member or the Registrar may, without referring the matter to the Board, issue a summons on behalf of the Board.

(3) A person who-

- (a) fails, without reasonable excuse, to comply with a summons issued to attend or to produce documents, records or equipment, before the Board;
- (b) having been served with a summons to produce a-
  - (i) written translation of the document or record into English; and
  - (ii) certificate signed by a translator approved by the Board certifying that the translation accurately reproduces in English the contents of the document or record,

fails, without reasonable excuse, to comply with the summons;

- (c) misbehaves before the Board, wilfully insults the Board or one or more of the members in the exercise of the members' official duties or wilfully interrupts the proceedings of the Board; or
- (d) refuses to be sworn or to affirm or refuses or fails to answer truthfully a relevant question when required to do so by the Board, commits an offence and is liable upon conviction to a fine of \$20,000.

(4) A person who appears as a witness before the Board has the same protection as a witness in proceedings before the High Court.

*Principles governing proceedings*

14. - (1) In any proceedings before the Board under this Decree, the Board-

- (a) is not bound by the rules of evidence and may inform itself on any matter as it thinks fit;
- (b) must act according to equity, good conscience and the substantial merits of the case without regard to technicalities and legal forms; and
- (c) must keep the parties to the proceedings properly informed as to the progress and outcome of the proceedings.

*Remunerations*

15. - (1) A member of the Board shall be entitled to be paid such remunerations and allowances as determined by the Minister.

(2) A professional person who is a member of the Board or of a committee is not entitled to charge professional fee for his or her attendance at meetings or for advice given as such a member.

*Costs*

16. - (1) The Board may award such costs against a party to proceedings before it, as the Board considers just and reasonable.

(2) A party who is dissatisfied with the amount of the costs awarded by the Board, may make an appeal in the High Court.

(3) Costs awarded by the Board under this section may be recovered as a debt.

*Funding of the Board*

17. - (1) The Board is funded out of fees for registration and other services provided by the Board as prescribed by the Regulations.

(2) The Board may at any time, receive public money by way of grant or loan from the government, in accordance with the Financial Management Act 2004.

*Accounts and audits*

18. - (1) The Board must keep proper accounting records in relation to its financial affairs and must have annual statements of account prepared in respect of each financial year.

(2) The accounts must be audited at least once in every year by an auditor approved by the Auditor-General and appointed by the Board.

(3) The Auditor-General may at any time, audit the accounts of the Board.

*Annual report*

19. - (1) The Board must, on or before the 30th of April every year, deliver to the Minister a report on the administration of this Decree in relation to its responsibilities and the work of the Board during the preceding financial year.

(2) The report must-

- (a) include in relation to the relevant financial year-

- (i) the number of products imported, manufactured, exported and registered during the year;
- (ii) the number of products withdrawn from the market;
- (iii) the number of importers, manufacturers, exporters and distributors licensed; and
- (iv) any other information prescribed by the Regulations;

(b) incorporate the audited accounts of the Board for the relevant financial year.

(3) The Minister must, within 28 days after receiving a report made under this section, have copies of the report laid before Cabinet.

#### PART 4 - FIJI MEDICINAL PRODUCTS BOARD SECRETARIAT

##### *Registrar of the Secretariat*

20. - (1) This section establishes the Fiji Medicinal Products Board Secretariat and the Chief Pharmacist, shall be the Registrar of the Secretariat.

(2) The Registrar shall report to the Chairperson of the Board.

##### *Other staff of the Secretariat*

21. - (1) The Board may, from time to time, appoint any such staff to the Secretariat, as it considers necessary to assist in the performance of its functions under this Decree.

(2) The staff of the Secretariat may include-

- (a) one or more Deputy Registrars or senior administrative officers;
- (b) persons responsible for communications with the public, including publications in the *Gazette*, websites, receiving enquiries and notifications about registered persons; or
- (c) a receptionist, data entry or clerical support staff.

(3) A member of the staff of the Secretariat is not, as such, a member of the Public Service, but the Board may employ a person who is on leave from employment in the Public Service or with an instrumentality or agency of the Government.

(4) The Board may, with the approval of the Minister responsible for the Public Service, make use of the services, facilities or officers of the Public Service.

##### *Functions of the Secretariat*

22. - (1) The Secretariat's functions are to-

- (a) provide administrative and secretarial services to and as directed by the Board and any committee established by the Board;
- (b) receive and process applications for licences and registration and refer every application duly made to the Board for decision;
- (c) implement decisions of the Board on registration, licensing and related matters;
- (d) maintain a website for the Board;
- (e) communicate with medicinal products and devices registration authorities in other jurisdictions, for the purpose of obtaining and supplying information about medicinal products and devices and applicants for licences; and

(f) perform other functions assigned to it by the Board, from time to time, in order to promote the objects of this Decree.

(2) The Secretariat may obtain and pay for legal services, information technology services and other services, for the better performance of its functions.

(3) The Registrar must ensure that all services are provided and that the business of the Board is conducted with transparency and as prescribed by this Decree and Regulations.

#### *Funding of the Secretariat*

23. - (1) The Secretariat is to be funded by the Board, from the fees for the registration of medicinal products, poisons and devices and for the granting of licences.

(2) The Secretariat must account to the Board, any fees or other moneys collected by it for services provided.

### PART 5 - COMMITTEES OF THE FIJI MEDICINAL PRODUCTS BOARD

#### *Committees*

24. - (1) The Board may, from time to time, establish such committees as it considers necessary or expedient to assist it in the performance of its functions under this Decree.

(2) The Board may appoint any person to be a member of any committee established under subsection (1), and shall appoint a Chairperson of the committee.

(3) A committee established under this section may regulate its own procedures and, in the exercise of its powers under this subsection, such committee shall be subject to and act in accordance with any direction given to the committee by the Board.

(4) Meetings of a committee established under this section shall be held at such times and places as the Chairperson of the committee may, subject to subsection (3), determine.

(5) A committee may invite any person for the purpose of advising it on any matter under discussion to attend any meeting of the committee, but the person so invited shall not be entitled to vote at any such meeting.

(6) The members of a committee or any person invited to attend any meeting of a committee may be paid such allowances and other expenses as the Board may determine, subject to approval by the Minister.

(7) The term of office of a person appointed to a committee under this section is as decided by the Board.

#### *Procedure of committees*

25. - (1) The procedures to be observed in relation to the conduct of the business of a committee are-

(a) as determined by the Board; and

(b) insofar as a procedure is not determined under paragraph (a) as determined by the committee.

(2) The quorum of a committee is a majority of its members unless the Board otherwise directs when appointing the committee.

(3) The Board may direct a committee to change its procedures or to adopt new procedures, if the Board considers it necessary to achieve efficient and accountable operation of the business of the committee.

(4) The Board may remove the Chairperson and members of the committee, if he or she-

- (a) ceases to be qualified to be appointed as a member;
- (b) conducts himself or herself in a manner that brings the profession into disrepute;
- (c) is absent from 3 consecutive meetings of the committee without reasonable excuse; or
- (d) fails to carry out or becomes incapable of performing satisfactorily, the duties of a committee member.

## PART 6 - CLASSIFICATION AND EXEMPTION OF PRODUCTS

### *Classification scheme*

26. - (1) For the purposes of this Decree, the Board may enact Regulations with different requirements and conditions applicable to the products.

(2) The Minister may, on the advice of the Board, by order published in the *Gazette*, classify other products depending on the considerations of safety and need.

(3) Without limiting subsections (1) and (2), the Minister may, with the advice of the Board, classify any substance or class of substances or admixture of substances under conditions and circumstances determined by the Minister, with respect to the-

- (a) quantity of the substance;
- (b) strength or dose of the substance;
- (c) presence or absence of any other substance when combined or mixed with the first named substance;
- (d) labelling or packaging of the substance; or
- (e) purpose for which the substance is to be used.

### *Minister may exempt*

27. - (1) The Minister may, by Order published in the *Gazette*, exempt any-

- (a) person or class of persons; or
- (b) product or class of products,

specified in the Order from such provisions of this Decree as are specified in the Order.

(2) An Order under subsection (1) is subject to the conditions, if any, specified in the Order.

(3) The Minister, by Order published in the *Gazette*, may amend, vary or revoke at any time, an Order made under this section.

(4) An Order under this section takes effect on the day on which it is published in the *Gazette* or on such later day as is specified in the Order.

*Declarations regarding substances*

28. - (1) If the Board is satisfied that a substance, class of substance or compound of substances-

- (a) is or is not a product; or
- (b) when used, advertised or presented for supply in a particular way, are or are not medicinal product or other product;

the Board may declare that the substance, class of substance or compound of substances, when used, advertised or presented for supply in that way, for the purposes of this Decree is-

- (i) a medicinal product or other product; or
- (ii) not a medicinal product or other product.

(2) A declaration under subsection (1) must be made by Order published in the *Gazette*.

(3) The Board may exercise its powers under this section-

- (a) of its motion;
- (b) at the request of the Chief Pharmacist; or
- (c) following a written application by any person to the Registrar.

(4) The Board, by Order published in the *Gazette*, may amend, vary or revoke at any time, a declaration made under this section.

PART 7 - THE REGISTRATION OF MEDICINAL PRODUCTS

*Requirement for registration*

29. - (1) Every medicinal product shall be registered with the Board.

(2) Subject to section 35, no person shall import, manufacture, export, store, sell, distribute, transport, offer for sale, expose to sale or advertise any medicinal product which is not registered with the Board under subsection (1).

*Registration process*

30. - (1) The Board shall, by notification published in the *Gazette*, require importers, manufacturers and exporters of medicinal products to provide such information as is specified in the notification concerning medicinal products imported into, manufactured in or exported from Fiji which such importers, manufacturers and exporters wish to continue to import, manufacture or export after such date, hereinafter referred to as the appointed date, as specified in the notification.

(2) Medicinal products in respect of which a notification has been received on or before the appointed date shall be listed on the Provisionally Authorised Medicinal Products Register.

(3) Medicinal products listed on the Provisionally Authorised Medicinal Products Register may be imported, manufactured, exported, stored, sold, distributed, transported, offered for sale, exposed to sale or advertised, unless and until the Board determines that any such medicinal product shall not be sold or imported into, manufactured in or exported from Fiji from such date as is mentioned in the determination.

(4) The Board shall review the medicinal products listed on the Provisionally Authorised Medicinal Products Register and either grant such products and devices registration status or direct that they be removed from the register.

(5) Medicinal products granted registration shall be entered on the Registered Medicinal Products Register. On the issuance of a certificate of registration, the relevant medicinal product or device shall be removed from the Provisionally Authorised Medicinal Products Register.

(6) No medicinal product which has been refused registration or removed from the Provisionally Authorised Medicinal Products Register other than for the reason referred to in subsection (5) above, shall be imported, sold, manufactured or exported from such date as is specified by the Board in its communication to the concerned importer, manufacturer or exporter.

(7) It shall be an offence for any person to sell, import, manufacture or export a medicinal product in contravention of subsections (3) and (6).

(8) A medicinal product not imported, manufactured or exported or otherwise available as at the appointed date, may be imported, manufactured or exported only with the approval of the Board and only after the Board has placed such medicinal product on the Registered Medicinal Products Register or Provisionally Authorised Medicinal Products Register.

(9) For the purposes of subsection (4), the Board shall be guided by considerations of quality, safety and efficacy but may also take into account other considerations relating to medical or public health needs and prices.

(10) The Board may, after granting an opportunity for the importer, manufacturer, exporter or such other person to make representations, suspend or cancel the registration status of a medicinal product or introduce conditions subject to which such medicinal product may be imported, manufactured, exported, stored, sold, distributed, transported, offered for sale, exposed to sale, promoted or advertised.

## PART 8 - THE REGISTRATION OF POISONS

### *Requirement for registration*

31. - (1) The provisions in Part 7 shall apply, *mutatis mutandis*, to poisons, from such date as is specified by the Board by notification published in the *Gazette* and accordingly, there shall be a Provisionally Authorised Poisons Register and a Registered Poisons Register.

(2) It shall be an offence for any person to sell, import, manufacture or export a poison that is not placed on the Registered Poisons Register or Provisionally Authorised Poisons Register or in contravention of any conditions imposed by the Board.

## PART 9 - THE REGISTRATION OF DEVICES

### *Requirement for registration*

32. - (1) The provisions in Part 7 shall apply, *mutatis mutandis*, to devices, from such date as is specified by the Board by notification published in the *Gazette* and accordingly, there shall be a Provisionally Authorised Devices Register and a Registered Devices Register.

(2) It shall be an offence for any person to sell, import, manufacture or export a device that is not placed on the Registered Devices Register or Provisionally Authorised Devices Register or in contravention of any conditions imposed by the Board.

## PART 10 - THE REGISTRATION OF OTHER PRODUCTS

### *Requirement for registration*

33. - (1) The provisions in Part 7 shall apply, *mutatis mutandis*, to any other product, hereinafter referred to as specified product, from such date as is specified by the Board by notification published in the *Gazette* and accordingly, for each such specified product, there shall be a relevant Provisionally Authorised Products Register and a Registered Products Register.

(2) It shall be an offence for any person to sell, import, manufacture or export such product that is not placed on the relevant Registered Products Register or Provisionally Authorised Products Register or in contravention of any conditions imposed by the Board.

## PART 11 - PROVISIONS APPLICABLE TO MEDICAL PRODUCTS OR POISONS SUBJECT TO AN INTERNATIONAL CONVENTION

### *Regulations to prescribe conditions*

34. - (1) The Minister shall, in consultation with the Board, issue Regulations prescribing the conditions subject to which medicinal products, substances, preparations or poisons, subject to any international convention may be-

- (a) imported, exported, trans-shipped, manufactured, transported, stored in an appointed dangerous drugs store and distributed; and
- (b) prescribed, dispensed and used.

(2) The Regulations shall specify the procedures, including special prescription and record keeping procedures, to be followed with regard to medicinal products, substances, preparations or poisons subject to an international convention.

## PART 12 - GENERAL PROVISIONS APPLICABLE TO MEDICINAL PRODUCTS, DEVICES AND POISONS

### *Licensing requirement*

35. - (1) No person shall import, manufacture or export any product without a licence issued by the Board.

(2) No person shall store, distribute, sell or offer for sale, any product without a licence issued by the Board, except a medicinal product, poison or device or other specified product which in the opinion of the Minister, is safe for general use and which is specified by Regulations made under this Decree.

(3) No person shall manufacture or prepare any product in any premises unless such premises have been licensed by the Board.

(4) No person shall store or sell any product in any premises unless such premises have been licensed by the Board, except such product which in the opinion of the Minister, is safe for general use and which is specified by Regulations made under this Decree.

*Insanitary conditions*

36. - (1) No person shall manufacture, prepare, preserve, package or store for sale, any product under insanitary conditions or any product which is adulterated or is a counterfeit.

(2) No person shall import, sell, distribute or offer for sale, any product that was manufactured, prepared, preserved, packaged or stored for sale under insanitary conditions, is adulterated or is a counterfeit.

(3) No person, other than a person specifically exempted by way of Regulations, shall obtain or have in his or her possession, any product which in the opinion of the Minister, is harmful to the health of the user and which is specified by Regulations made under the Decree.

*Labels and packaging*

37. - (1) No person shall label, package, treat, process, sell, distribute, offer for sale or advertise any product in a manner that is false, misleading, deceptive, or likely to create an erroneous impression regarding its character, value, potency, quality, composition, merit or safety.

(2) A product that is not labelled or packaged as required by the Regulations made under this Decree or is labelled or packaged contrary to such Regulations, shall be deemed to be labelled or packaged contrary to subsection (1).

*Standards*

38. - (1) Where a standard is prescribed for any product, no person shall label, package, sell, offer for sale, distribute or advertise any product which does not conform to such standard in such a manner as is likely to be mistaken for the product for which a standard has been prescribed.

(2) Where a standard has not been prescribed for any product but a standard for that product is contained in any publication set out in Regulations made under this Decree, no person shall label, package, sell, offer for sale, distribute, or advertise any product which does not conform to the standard contained in that publication in such a manner as is likely to be mistaken for the product for which the standard is contained in that publication.

(3) Where a standard has not been prescribed for any product or a standard for that product is not contained in any publication specified in Regulations made under this Decree, no person shall sell, offer for sale or distribute such product-

- (a) unless it is in conformity with the standard set out in the label accompanying the product; or
- (b) in such a manner as is likely to be mistaken for a product for which a standard has been prescribed or for which a standard is contained in any publication specified in Regulations made under this Decree.

*Distribution of samples*

39. No person shall distribute or cause to be distributed any product as a sample unless it is distributed under prescribed conditions to a medical practitioner, dentist or veterinary surgeon.

*Advertisements and promotion*

40. No person shall advertise or promote any product to the public as a treatment, prevention or cure for any diseases, disorders or abnormal physical state unless such advertisement or promotion is in accordance with the conditions set out in the Regulations.

## PART 13 - ENFORCEMENT

### *Appointment of authorised officers*

41. - (1) The Minister may, authorise the following persons to be authorised officers for the purposes of all or any of the provisions of this Decree-

- (i) any officer or class of officer, person or class of person employed in the Ministry; or
- (ii) any other person or class of person with appropriate qualifications or expertise.

(2) Every authorised officer shall exercise the powers conferred upon him or her, for the purpose of discharging his or her duties under this Decree.

### *Powers of authorised officers*

42. - (1) For the purposes of this Decree, an authorised officer may-

- (a) at any reasonable time, enter any place where he believes any product is manufactured, prepared, packaged, preserved or stored and examine any such product and take samples thereof and also examine anything that he or she believes is used for the manufacture, preparation, preservation, packaging or storing of such product;
- (b) open and examine any receptacle or package that he or she believes to contain any product;
- (c) examine any books, documents or other records found in any place mentioned in paragraph (a) that he or she believes to contain any information relevant to the carrying into execution of the enforcement of this Decree, with respect to any product and make copies thereof or take extracts there from;
- (d) seize and detain for such time as may be necessary, any product by means of or in relation to which he or she believes any provisions of this Decree or Regulations made thereunder have been contravened; and
- (e) examine and seize anything used or capable of being used for the manufacture, preparation, preservation, packaging or storing of any drug including any labelling or advertising material.

(2) Any authorised officer acting under this section shall, if so required, produce his or her authority.

(3) The owner or person in charge of a place entered by an authorised officer, in pursuance of subsection (1) and every person found therein, shall give the authorised officer, all reasonable assistance in his or her power and furnish him or her with such information and such samples as he or she may require.

(4) No person shall obstruct any authorized officer acting in the exercise of his or her power under this Decree or any Regulations made thereunder.

(5) If any authorised officer applies to obtain samples of any product exposed for sale and the person exposing the product refuses to sell to the authorised officer such quantity thereof as he or she may

require or refuses to allow that officer to take the quantity which he or she is empowered to take, the person refusing shall be deemed, for the purpose of subsection (5) to have obstructed an authorised officer.

(6) No person shall knowingly make a false or misleading statement either orally or in writing to any authorised officer engaged in the exercises of his or her powers under this Decree or any Regulations made thereunder.

(7) No person shall remove, alter, tamper or otherwise interfere in any manner with any product seized under this Decree by an authorised officer, without the authority of the authorised officer.

(8) Any product seized under this Decree may, at the discretion of the authorised officer, be kept or stored in the building or place where it was seized or be taken to any other place.

(9) An authorised officer shall inform the Registrar, of any seizure made under this Decree.

#### *Dealing with seized products*

43. - (1) Where the Board is satisfied that there has been a contravention of any of the provisions of this Decree or Regulations made thereunder, it may direct any authorised officer to seize, destroy or dispose of such product, provided that the owner of such product or the person in possession of such product, at the time of seizure, consents in writing to the destruction of such product.

(2) Where the owner or person in possession of such product, does not consent in writing to the destruction of such product, the Board shall-

- (a) release such product if it is satisfied that the provisions of this Decree or any other Regulations made thereunder, in respect of such product have not been contravened; or
- (b) where it is satisfied that there has been contravention of any of the provisions of this Decree or Regulations made thereunder, forthwith, with notice to such owner or person in possession of the product, inform the court having jurisdiction over the matter, of the seizure of the product in respect of which the offence was committed.

(3) On information furnished to the court under subsection (2) (b), such court shall if, after trial, it finds the owner or person in possession of the product-

- (a) guilty of contravening any of the provisions of this Decree or Regulations made thereunder, order that such product be forfeited to the Board, to be disposed of as the court may direct, provided however, that where the offender is not known or cannot be found, such product shall be forfeited to the Board without the institution of proceedings in respect of such contravention; or
- (b) not guilty of contravening any of the provisions of this Decree or Regulations made thereunder, order that such product be released to such owner or person in possession.

#### *Analysis of products*

44. - (1) An authorised officer shall submit any product, portion thereof or any sample seized by him or her, unless destroyed under section 43, to the Government Analyst for analysis or examination.

(2) Where the Government Analyst has made an analysis or examination of the product submitted to him or her under subsection (1), he or she shall issue a certificate or report to the Registrar, setting out the results of his or her analysis or examination.

#### *Designation of Analysts*

45. - (1) For the purposes of this Decree and the Regulations made thereunder, the Government Analyst shall be the Approved Analyst.

(2) Notwithstanding the provisions of subsection (1), the Minister may approve any person to be an additional Approved Analyst and notification of the approval shall be published in the *Gazette*.

(3) No person shall be approved as an additional Approved Analyst if he or she does not possess the prescribed qualifications.

#### *Penalties*

46. - (1) Every person who contravenes any of the provisions of this Decree or any Regulations made thereunder or fails to comply with any direction given under this Decree or Regulations, shall be guilty of an offence and shall be liable on conviction-

- (a) where the nature of the offence involves injury to the health of the public, to a fine not exceeding \$5,000 or to imprisonment for a term not exceeding 3 years or both; or
- (b) for any other offence-

- (i) for the first offence, a fine not exceeding \$1,000 or to imprisonment for a term not exceeding 3 months or both; or
- (ii) for a second or subsequent offence, a fine not exceeding \$2,000 or to imprisonment for a term not exceeding 6 months or both.

(2) Where a person is convicted of a second or subsequent offence under this Decree or any Regulations made thereunder, the court may, for the second or subsequent offence-

- (a) cause the name and address of the person convicted and the offence and the punishment imposed for such an offence to be published in such a newspaper or in such a manner as the court may direct and recover the cost of publication from the person convicted as if it were a fine imposed on him; or
- (b) cancel any licence, permit or authorisation issued to the person convicted for the manufacture, importation, sale and distribution of any product under this Decree and inform the relevant licensing authority accordingly.

#### *Arrest*

47. Any person who commits an offence under this Decree or any Regulations made thereunder, in dealing negligently with a product that poses a serious risk to the health of a consumer, shall be arrested with a warrant and every offence under this Decree or Regulations shall be triable in the appropriate court.

#### *Search warrants*

48. - (1) If a Magistrate is satisfied by information on oath that there is reasonable cause to suspect that any place has been or is being or is likely to be used in connexion with a contravention of this Decree or for the keeping of records relating to a contravention of this Decree, he or she may issue the search warrant to any authorised persons to enter and search such premises or place for the purpose of exercising therein, the powers conferred by this Decree.

(2) No provision of this section shall be taken to authorise forcible entry by any authorised persons, under section 49, to any premises save under the authority of a warrant obtained by him or her pursuant to subsection (1).

(3) A search warrant issued under this section shall, for a period of one month from its issue, be sufficient authority, to any authorised persons, to whom it is directed, to-

- (a) enter the place specified in the search warrant; and
- (b) exercise in respect of the place specified in the search warrant all the powers conferred by this Decree.

*Power of entry, search and seizure*

49. For the purposes of this Decree and subject to section 48, any authorised persons may-

- (a) enter any office or premises at any time that the performance of his or her functions requires such entry;
- (b) when entering any office or premises, take with him or her such equipments and materials as he or she considers contravenes the provisions of this Decree;
- (c) search any person if he or she reasonably suspects that such person is guilty of any of the offences under this Decree;
- (d) require the production and examination of any document and take copies or extracts of any document, or part of any document relating to products; or
- (e) seize and detain anything which any Board member or authorised persons has reason to believe to be or to contain evidence of any of the offences under this Decree.

*Obstruction*

50. - (1) A person shall not obstruct any authorised persons, in the exercise of his or her powers under this Decree.

(2) For the purposes of this Decree, a person shall be deemed to obstruct any authorised persons, in the exercise of his or her powers, if he or she-

- (a) directly or indirectly prevents any person from being questioned or from furnishing under this Decree, any information or records or copies thereof or attempts to do so; or
- (b) in any other way obstructs or attempts to obstruct authorised persons.

(3) Any person who contravenes this section shall be guilty of an offence.

*Institution of prosecutions*

51. A prosecution for an offence under this Decree or any Regulations, shall not be instituted except with the sanction of the Board.

PART 14 - MISCELLANEOUS PROVISIONS

*Regulations*

52. - (1) The Minister, after consulting the Board, may make any Regulations required, necessary or expedient, for the purposes of this Decree.

(2) The Minister, may make Regulations for or with respect to-

- (a) prohibiting or regulating the possession, manufacture, sale, supply, distribution or use of any product either absolutely or in prescribed circumstances or conditions;

- (b) without limiting paragraph (a), prohibiting or regulating a person from having in his or her possession, manufacturing, selling, distributing or using any product or class of product unless the person is authorised by or licensed or permitted under this Decree or the Regulations so to do;
- (c) prescribing precautions to be taken in and regulating or controlling the manufacture, storage, use or handling of any product;
- (d) prescribing penalties not exceeding \$1,000 for any contravention of the Regulations;
- (e) prescribing forms to be used;
- (f) prescribing fees to be paid;
- (g) the sale, supply and safe custody of products, including-
  - (i) the specifications of cupboards and other receptacles and the manner of storage of any product;
  - (ii) the procedure to be followed in relation to the sale or supply and recording of product;
  - (iii) prohibiting the sale or supply of any product by self service methods or vending machines other than any methods prescribed; or
  - (iv) the colouring of any product;
- (h) prohibiting or regulating the sale or supply of any product (whether by wholesale or by retail) or any class of products containing any particular substance, ingredient or preparation unless-
  - (i) packaged in accordance with Regulations made under this Decree; or
  - (ii) containing no more than a specified concentration of any specified substance, ingredient or preparation;
- (i) specifying-
  - (i) the minimum size of packages or containers in which products or any class of products may be sold or supplied or offered for sale or supply;
  - (ii) the containers in which any product may be sold or supplied and prohibiting the use of such containers for other substances; or
  - (iii) labelling and the particulars, including antidotes, to be included in labels attached to containers of products;
- (j) prohibiting and controlling advertising by any person in relation to products;
- (k) applications, issue, renewal, amendment, suspension or cancellation of licences, permits, and authorities issued under this Decree;

- (l) prescribing terms, conditions, limitations and restrictions to which licences, permits and authorities issued under this Decree are subject to;
- (m) the inspection of premises, stocks, books and any other documents relating to products;
- (n) exempting from all or any of the provisions of this Decree and the Regulations, any product containing substances or preparations which by their nature is not capable of being used in evasion of this Decree;
- (o) specifying the persons or classes of persons authorised or entitled to purchase, obtain, use or be in possession of any product;
- (p) providing the persons who are authorised or entitled to purchase, obtain or have in their possession or use specified products or specified classes of products;
- (q) providing for the disposal of automatic machines forfeited under this Decree;
- (r) prescribing a penalty not exceeding \$1,000 for any contravention of or failure to comply with the Regulations, terms or conditions of a licence, permit or other authority under this Decree or Regulations; or
- (s) generally prescribing all such matters and things as are authorised or required to be prescribed or are necessary or convenient to be prescribed for carrying into effect the objects of this Decree.

(3) Without limiting subsection 2, the Regulations may-

- (a) prescribe fees or charges for-
  - (i) the purposes of this Decree; or
  - (ii) services provided by the Board in the exercise of its functions under this Decree;
- (b) exempt any class of persons from the obligation to pay a fee or charge so prescribed;
- (c) prescribe forms for use in connection with this Decree;
- (d) make further provision with respect to the keeping of a register;
- (e) prescribe penalties not exceeding \$5,000 for the breach of any Regulations;
- (f) be of general or limited application;
- (g) make different provisions according to the persons, products, things or circumstances to which they are expressed to apply; or
- (h) provide that a specified provision of this Decree does not apply or applies with prescribed variations, to any person, product, circumstance, situation or person, product, circumstance or situation of a prescribed class specified in the Regulations, subject to any condition to which the Regulations are expressed to be subject to.

(4) Regulations under this Part may apply, adopt or incorporate by reference to any convention, scheme, resolution or document formulated or published by a person or body, including the United Nations and World Health Organisation either-

- (a) without modification or as modified by the Regulations;
- (b) as formulated or published on or before the date when the Regulations were made; or
- (c) as formulated or published from time to time.

(5) If a code, standard or other document is referred to or incorporated in the Regulations-

- (a) a copy of the code, standard or other document must be kept available for public investigation without charge, during normal office hours, at an office or offices specified in the Regulations; and
- (b) evidence of the contents of the code, standard or other document may be given in any legal proceedings by production of a document apparently certified by the Minister, to be a true copy of the code, standard or other document.

#### *Codes of conduct and professional standards*

53. - (1) Subject to the approval of the Minister, the Board may prepare or endorse a code of conduct or a professional standard in relation to the importation, exportation, manufacture, sale, advertising, promotion or pharmacy practice.

(2) The Board may issue guidelines relating to good procurement, storage, prescribing and dispensing practices.

(3) If a code of conduct or professional standard prepared or endorsed by the Board is approved by the Minister or guidelines are issued by the Board, the Board must ensure that a copy of the code, standard or guidelines is published-

- (a) in the *Gazette*; and
- (b) on the internet and kept available for public investigation without charge, during normal office hours, at the principal office of the Board.

(4) Proof of compliance with subsection (3) is not necessary for the purposes of any proceedings that involve an alleged contravention of or failure to comply with a code of conduct or professional standard or guidelines.

#### *Confidentiality*

54. - (1) A person engaged or formerly engaged in the administration of this Decree or the repealed sections of the corresponding legislation must not divulge or communicate personal information obtained, whether by that person or otherwise, in the course of official duties except-

- (a) as required or authorised by or under this Decree or the repealed Act;
- (b) in the performance of duties under this Decree or any other written law;
- (c) to an authority responsible under the law of a place outside Fiji for the regulation of products to which and the persons to whom the Decree applies if the information is required for the proper administration of that law; or
- (d) with the consent of the person to whom the information relates.

(2) Subsection (1) does not prevent disclosure of statistical or other data that could not reasonably be expected to lead to the identification of any product or person to whom it relates.

(3) Information that has been disclosed under subsection (1) for a particular purpose, must not be used for any other purpose by-

- (a) the person to whom the information was disclosed; or
- (b) any other person who gains access to the information, whether properly, improperly, directly or indirectly, as a result of that disclosure;

(4) A person who discloses information in contravention of subsection (1) commits an offence and is liable upon conviction to a maximum penalty of a fine of \$10,000.

#### *Service*

55. A notice or document required or authorised to be given, sent to or served on a person, for the purposes of this Decree may be-

- (a) given to the person personally;
- (b) posted in an envelope addressed to the person at the person's last known nominated contact, residential, business or in the case of a corporation, the registered address;
- (c) left for the person at the person's last known nominated contact, residential, business or in the case of a corporation, the registered address with someone apparently over the age of 16 years; or
- (d) transmitted by facsimile transmission or electronic mail to a facsimile number or electronic mail address provided by the person, in which case the notice or document, will be taken to have been given or served at the time of transmission.

#### *Evidentiary provisions*

56. - (1) In proceedings for an offence under this Decree, an allegation in the complaint that-

- (a) a person named in the complaint is, is not, was or was not, on a specified date, a registered person;
- (b) the registration of a person named in the complaint is or was on a specified date, subject to specified conditions; or
- (c) a medicinal product, poison or device is, is not, was or was not on a specified date, on the Registered or Provisionally Authorised Medicinal Products, Poisons or Devices Register, as the case may be,

must be accepted as proved in the absence of proof to the contrary.

(2) In legal proceedings, a document apparently certified by the Registrar of the Secretariat to be a copy of a register under this Decree or a copy of a code of conduct or professional standard prepared or endorsed by the Board under this Decree, must be accepted as such in the absence of proof to the contrary.

#### *Statutory Declarations*

57. If a person is required to furnish information to the Secretariat, the Secretariat may require that the information be verified by Statutory Declaration and in that event, the person will not be taken to have furnished the information as required unless it has been verified in accordance with the requirements of the Secretariat.

## PART 15 - REPEALS, SAVINGS AND TRANSITIONAL

### *Repeals and savings*

58. Notwithstanding the repeal of the Pharmacy and Poisons Act (Cap. 115), the Regulations made under that Act and in force immediately before the coming into operation of this Decree, shall, except where so far as they are not inconsistent with the provisions of this Decree, continue in force until altered, amended, or rescinded by Regulations made under this Decree.

*Transitional provisions*

59. - (1) A registered medical practitioner, dentist or veterinary surgeon may prescribe and continue to dispense medicinal products in accordance with the provisions of this Decree and the Regulations and the National Medicinal Products Policy.

(2) A prosecution for an offence committed against a repealed law must be brought and continued under that law.

(3) Subject to subsection (2), any action, arbitration, proceeding or cause of action that relates to the functions of the Pharmacy and Poisons Board, that immediately before the commencement of this Decree is pending or existing by, against or in favour of the Pharmacy and Poisons Board, or to which the Pharmacy and Poisons Board is a party, may be continued and enforced by and against the Pharmacy and Poisons Board under the provisions of this Decree.

**GIVEN under my hand this ..... day of ..... 2011.**

.....  
**EPELI NAILATIKAU**  
**President of the Republic of Fiji**