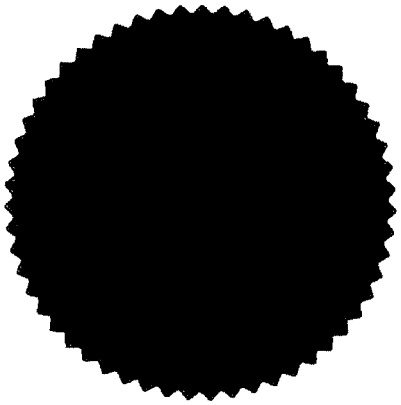
**REPUBLIC OF KIRIBATI**
(No.1 of 2018)



I assent,
Beretitenti

13/10/18

**AN ACT**
entitled

An Act to protect public health by providing for the establishment of the Medicines and Therapeutics Committee and for the effective regulation of medicines in Kiribati to ensure their quality, safety and efficacy.

Commencement:

2018

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PART 1 – PRELIMINARY

1. Short title
This Act may be cited as the Medicines Act 2018.

2. Commencement
This Act comes into force on a date appointed by notice by the Minister.

3. Act binds Government
This Act binds the Republic.

4. Definition
In this Act, unless the context otherwise requires -

'**administer**' means administer to a human being, either orally or by injection or by introduction into the body in any other way; or by external application, whether by direct contact with the body or not;

'**advertisement**' means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of medicines or the use of any method of treatment; and advertises has a corresponding meaning;

'**animal health officer**' means an officer responsible for veterinary services within the ministry responsible for the administration of environment, lands and agricultural development;

'**authorised officer**' means a Committee member or a person appointed by the Committee to be an authorised officer under section 9;

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

'**Chief Pharmacist**' means the Chief Pharmacist of the ministry responsible for the administration of health and medical services, or any person acting for the time being in such position;

'**clinical trial**' means any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes;

'**Committee**' means the Medicine and Therapeutics Committee established by this Act;

'**court**' means the Magistrate's Court and the High Court;

'**counterfeit**' in relation to medicines or starting materials, means a medicine or substance which is deliberately and fraudulently mislabelled with respect to identity or source;

'**dentist**' means a person who is duly registered as such under the *Medical Services Act* 1996;

'**dispensing**' means the preparation of a medicine for sale to the public and the packaging, labelling, recording, and supply of that medicine;

'**health professional**' means a medical practitioner and includes persons who are 'registered persons' under section 2 of the *Medical Services Act* 1996;

'**importer**' means any person by or for whom any goods are imported; and includes the consignee of any goods; and also includes any person who is or becomes —

a. the owner of any goods; or

b. entitled to the possession of any goods; or

c. beneficially interested in any goods

on or at any time after the importation of those goods and before they have ceased to be subject to the control of Customs in accordance with the *Customs Act* 2005;

'**label**' in relation to a container of a medicine, means any written, pictorial, or other descriptive matter marked on or affixed to the container; and labelled has a corresponding meaning;

'**licence**' means a licence issued under this Act; and licensed and licensee have corresponding meanings;

'**manufacture**' in relation to a medicine, includes any process carried out in the course of making the product;

'**medical assistant**' means a person who is duly registered as such under the *Medical Services Act* 1996;

'**medical practitioner**' means a person who is duly registered as such under the *Medical Services Act* 1996;

'**medicine**' means any substance whether of animal, plant or synthetic origin (not being a medicinal device) which is used internally or externally in humans or animals for a medicinal purpose, including –

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;

'**Medicine Schedule**' means the schedule established under section 12 of this Act by which registered medicines are classified in order to prescribe how such products may be made available to the public;

'**Medicinal device**' means goods 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 is intended to be used in, on, or for human beings for a therapeutic purpose and 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;

'**midwife**' means a person who is duly registered as such under the *Medical Services Act* 1996;

'**Minister**' means the Minister responsible for the administration of health and medical services;

'**Ministry**' means the Ministry responsible for the administration of health and medical services;

'**new medicine**' means a medicine which has not yet been registered by the Committee and listed on the Register of Medicines;

'**nurse**' means a person who is duly registered as such under the *Medical Services Act* 1996;

'**package**' in relation to any medicine, means any box, packet, or other article in which a container of the medicine are or are to be cased, covered, enclosed, or contained;

'**pharmacist**' means a person who is duly registered as such under the *Medical Services Act* 1996;

'**prescription**' means the written order in an approved form and issued by a medical practitioner or dentist for the supply of a medicine to any person;

'**Register of Medicines**' means the register, established under section 11 of this Act, of medicines approved for use in Kiribati;

'**regulations**' means regulations made under this Act;

'**Secretary**' means the Secretary responsible for the administration of health and medical services;

'**sell**' includes -

a. barter and exchange;

b. offering or attempting to sell, or having in possession for sale, or exposing for sale, or sending or delivering for sale, or keeping or having in possession for sale, or sending, forwarding, delivering or receiving for sale or on sale, or authorising, directing, causing, suffering, permitting or attempting any such acts; and

c. supplying by way of gift or sample for the purpose of promoting a sale,

whether by wholesale or retail, and sale has a corresponding meaning;

'**supply**' means to sell, or agree to sell, offer, advertise, expose, transmit, convey, deliver, make or prepare for sale, hire, exchange or dispose of for any consideration, transmit, convey or deliver pursuant to a sale, exchange or disposal, or to have in possession for any purposes referred to in this definition;

'**substantial adverse effect**' means a significant response to a medicine which is harmful and unintended, including lack of efficacy, and which occurred at normal human dosage;

'**veterinary surgeon**' has the same meaning as the expression 'approved veterinary surgeon' in section 2 of the *Dangerous Drugs Ordinance* (Cap. 32).

5. Application
The provisions of this Act extend to all persons, both public and private sector engaged in manufacturing, importing, exporting, prescribing, compounding, storing, distributing, promoting, supplying or in any other way dealing with medicines.

6. Object of this Act
The object of this Act is to protect public health by providing for the effective regulation of medicines in Kiribati to ensure their quality, safety and efficacy.

## PART 2 – THE MEDICINES AND THEREAPEUTICS COMMITTEE

7. Establishment

There is hereby established a body called the Medicines and Therapeutic Committee, in this Act referred to as 'the Committee'.

8. Functions

The functions of the Committees shall be to:

a. develop, implement and monitor the National Medicines Policy;

b. establish, maintain and annually revise the Register of Medicines;

c. schedule all medicines in the Register of Medicines in accordance with the Medicine Schedule;

d. assess applications and grant licences for medicines to be manufactured, imported into, exported from, prescribed, compounded, stored, distributed, or supplied in Kiribati and maintain a register of such licence-holders;

e. cancel the registration of, or cause to be recalled from the market, medicines which if continued to be used may be detrimental to public health;

f. sample, analyse, or otherwise test or arrange for testing of medicines released into the distribution chain, to ensure their compliance with labelled specifications;

g. monitor the market, including through inspection of premises, to ensure that standards are being maintained and to check for the presence of illegal or counterfeit medicines;

h. ensure that the promotion and marketing of medicines is in accordance with medicine information as approved by the Committee;

i. disseminate information on medicines to the health professions in order to promote their rational use;

j. collect registration and licence application and renewal fees;

k. monitor and review the implementation of the legislation;

l. establish a database to record and monitor drug side effects and reactions based on reports provided by health professionals and make appropriate related decisions; and

m. advise the Minister on matters concerning control and registration of medicines and guidelines, standards and regulations under this Act and propose amendments as deemed necessary.

9. Composition, structure and meetings

1) The Committee shall be comprised of the following members:

a. Director-General of Health;

b. Director of Hospital Services;

c. Chief Pharmacist;

d. Director of Public Health;

e. Director of Nursing;

f. Director of agriculture and livestock division, from Ministry responsible for the administration of agriculture and livestock;

g. A medical practitioner or pharmacist from the private sector as appointed by the Minister; and

h. any other medical or pharmaceutical practitioner as appointed by the Minister to serve on the Committee for such term and for such purposes as the Minister thinks fit.

2) The Minister shall appoint members of the Committee.

3) The Minister may cancel the appointment of any appointed member and appoint another person in place of such member for the remaining period of office.

4) The appointed members of the Committee shall hold office for a period of 3 years and shall be eligible for reappointment.

5) The Director-General of Health, and if this position is vacant, the Director of Hospital Services, shall be the chairperson of the Committee.

6) The Chief Pharmacist shall be the secretary of the Committee.

7) The powers of the Committee shall not be affected by any vacancy in its membership.

8) The Committee shall meet as required and at least 4 times a year.

9) At any meeting of the Committee, half of the members shall form a quorum.

10) The Committee shall determine the procedures and rules governing its meetings.

11) Any member of the Committee who has a personal 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.

12) The Committee shall prepare an annual report to the Minister which contains a report on the activities of the Committee in the preceding 12 months and a financial statement of accounts.

13) The Committee shall appoint such other officers as may be necessary to assist it to perform duties and to exercise powers under this Act. Such officers shall be known as 'authorised officers'.

14) An act in good faith and without negligence by the Minister, any Committee member or an authorised person shall not subject that person to any personal liability.

## PART 3 – REGISTER OF MEDICINES

10. Declarations

1) When requested or at its own volition, the Committee may make a declaration that a particular substance, class of substance or compound of substances, for the purposes of this Act, is:

a. a medicine; or

b. not a medicine.

2) The Committee may by order, when it considers necessary to do so in the interests of public safety, prohibit the supply or importation of a medicine.

11. Register of Medicines

1) In accordance with the approved national medicines policy and Kiribati's health care needs, and in consideration of the quality, safety and efficacy of medicines, every medicine approved for use in Kiribati shall be registered with the Committee.

2) The Committee shall maintain a Register of Medicines and shall cause this list to be published in Kiribati so that it is readily available to the health profession and the public.

3) The Register of Medicines shall comprise of two lists:

a. the Kiribati Essential Medicines List (which shall specify the registered medicines necessary to satisfy the public health needs in Kiribati); and

b. the Kiribati List of Other Registered Medicines (which shall specify other medicines which the Committee has approved for use in Kiribati).

4) The Committee shall annually review the content and may make amendments to the Register of Medicines.

12 Medicine Schedule

1) The Committee shall schedule every registered medicine in a category of medicine in accordance with the Medicine Schedule.

2) In scheduling medicines, the Committee must take into account:

a. whether the medicine is likely to present a direct or indirect danger to human health even when used correctly, if used without the supervision of a doctor or dentist; or

b. whether the medicine is frequently used incorrectly, and as a result is likely to present a direct or indirect danger to human health.

3) The Medicine Schedule shall classify medicines into the following categories:

a. Level 1: medicines which are available from licensed retail outlets without prescription;

b. Level 2: medicines which may be dispensed or administered by nurses without prescription;

c. Level 2B: medicines which may be dispensed or administered by or under the supervision of medical assistants without prescription;

d. Level 3: medicines which must be prescribed by medical practitioners and dispensed by pharmacists;

e. Level 4: Narcotic and psychotropic medicines which must be prescribed by medical practitioners in accordance with the Controlled Drugs Prescribing Policy for Narcotic and Psychotropic substances, and dispensed by pharmacists;

f. Level D: medicines which must be prescribed by dentists and dispensed by pharmacists; and

g. Level V: medicines which must be prescribed and dispensed by veterinary surgeons or animal health officers.

13. Application for new medicine registration

1) A person may apply to the Committee for registration of a new medicine and the proposed classification of the medicine.

2) Any application for a medicine registration must be made in the manner and form set out in regulations under this Act, which shall specify the standards to which medicines are to conform, the documentation to be provided to obtain registration and any application fees.

14. Criteria for registration

1) A medicine will only be registered if the Committee is satisfied that the medicine:

a. is of acceptable quality;

b. meets an acceptable safety profile;

c. is of demonstrated efficacy;

d. is appropriate for use in Kiribati; and

e. has satisfactory registration or approval status with international regulators.

2) In deciding whether a medicine should be registered, the Committee may consult relevant authorities and health professionals and take into account regulatory information from other countries and relevant international organisations.

3) The Committee may impose conditions on the registration of new medicines, including a requirement on the manufacturer to notify the Committee of any material changes made to the medicine.

15. Cancellation, suspension or variation of registration

1) The Committee may at any time cancel, suspend or vary the registration of a medicine, either with immediate effect or from such date as specified by the Committee.

2) When the Committee orders that a registration is to be cancelled, suspended or varied, the order of the Committee may specify how the order is to take effect, particularly with regard to recalling the medicine from the market and the procedures, if any, for notifying health professionals and the public.

3) On a decision to grant, cancel, suspend or vary a registration under this section taking effect, the Committee shall update the Register of Medicines.

16. Application for a review

1) Any person who is aggrieved by an order made by the Committee may appeal to the Minister in writing, within 14 days from the date of the order.

2) The Minister shall consult within the Ministry and may direct the Committee to rescind, suspend, vary, modify, or reconsider the order against which the appeal has been lodged.

## PART 4 – CONTROLS ON DEALINGS WITH MEDICINES

17. Requirement to be authorised or licensed

1) A person commits an offence if he or she manufactures, imports, exports, prescribes, compounds, stores, distributes, or supplies a medicine and:

a. the medicine is not registered in the Register of Medicines; or

b. the person is not authorised or licenced to do so under Part 4 of this Act.

2) For the avoidance of doubt, any person, including a person authorised under section 18 or 19 to prescribe, supply, dispense or administer particular levels of medicine, must be licensed to manufacture, import or export medicine.

3) Regulations made under this Act may prescribe standard licence provisions and categories, and applicable terms and conditions applying to those categories.

18. Authority to prescribe medicine

1) The following people are authorised to prescribe medicines, subject to the Medicine Schedule restrictions set out below:

a. Medical practitioners are authorised to prescribe any scheduled level of medicines for particular persons under their care.

b. Dentists are authorised to prescribe Level D medicines for particular persons under their care.

c. Veterinary surgeons and animal health officers are authorised to prescribe Level V medicines for animals under their care.

19. Authority to supply, dispense and administer medicine

1) The following people or entities are authorised to deal with medicines, subject to the restriction in reference to the Medicine Schedule set out below:

a. Licenced retail outlets which are registered under the *Registration of Business Names Act 1988* and the *Companies Ordinance Cap 10A* may supply Level 1 medicines;

b. Nurses may dispense and administer Level 1 or Level 2 medicines for particular persons under their care;

c. Medical assistants, and nurses being supervised by medical assistants, may dispense and administer Level 1, Level 2 or Level 2B medicines for particular persons under their care;

d. Medical practitioners may administer any medicine listed on the Medicine Register for particular persons under their care;

e. Pharmacists may obtain, compound, prepare, store, distribute, supply or dispense any medicine listed on the Medicine Register; and

f. Veterinary surgeons and animal health officers are authorised to administer Level V medicines for animals under their care.

20. Exemptions

1) Despite section 17, a medicine not included in the Register of Medicines may be imported without a licence:

    a. when that importation is for personal medicinal use, evidenced by a letter or certificate of that person's medical practitioner registered outside Kiribati; or

    b. upon application by a registered medical practitioner or pharmacist, if the Minister authorises (by written notification) the importation of a medicine not included in the Register of Medicines to meet:

        i. the particular treatment needs of an individual patient; or

        ii. public health needs during a major disaster or period of emergency.

2) The giving of an authorisation under subsection 1 shall not render the Government, the Minister or the Committee 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 the medicine.

3) Despite section 17, donated medicines may be imported into Kiribati without a licence if:

    a. the medicines are on the Kiribati Essential Medicines List;

    b. the prospective donations are fully detailed and approved by the Committee before dispatch of the donation; and

    c. any other requirements as made by the Committee are satisfied.

21. Application for licence

1) A person may apply to the Committee for a licence to manufacture, import, export, store, distribute or supply a medicine.

2) A licence application shall:

    a. be made in the manner and form specified in regulations under this Act and contain, or be accompanied by, such information, documents, and other material as may be prescribed;

    b. identify the medicines that the applicant wishes to deal with and the relevant classification according to the Medicine Schedule;

    c. specify how the applicant intends to deal with the medicines; and

    d. be accompanied by the prescribed application fee.

3) The Committee may at any time, require the applicant to allow an authorised officer to inspect the premises, equipment and facilities that are or will be used for the storage or supply of medicines.

22. Grant, refusal, cancellation, suspension or variation of licence

1) Subject to the following provisions of this Act, on any application to Committee under this Part of this Act, the Committee:

    a. may grant a licence subject to such conditions as it considers appropriate; or

    b. refuse to grant a licence.

2) If granted, the licence shall be in writing and shall:

   a. specify the particular medicine or the scheduled level of medicine which the licence holder is authorised to deal with;

   b. specify the way in which the licence holder may deal with the medicines;

   c. require the licence holder to allow an authorised officer to enter the premises to where the medicines are imported or sold and to inspect those premises and inspect and/or sample any medicines stored at those premises;

   d. be non-transferable; and

   e. impose any other conditions as the Committee thinks fit.

3) A single licence may authorise the licence holder to deal:

   a. with multiple medicines;

   b. with multiple scheduled levels of medicine; or

   c. with the medicine in multiple ways.

4) A licence commences on the day specified in the licence and remains in force until it is revoked or suspended, or as otherwise specified in the licence.

5) (i) The Committee will grant an applicant a licence if the Committee is satisfied that:

   a. the application requirements were complied with;

   b. the applicant has sufficient knowledge of the obligations of a licensee and of the risks associated with the medicines to which the licence would relate;

   c. if applicable, the premises of the applicant are appropriate for the purposes for which the licence is sought; or

   d. the applicant or a body corporate currently or previously controlled by the applicant (directly or indirectly) has not been convicted of an offence against this Act, the *Medical Services Act* 1996, the *Pharmacy and Poisons Ordinance* (Cap. 70), the *Dangerous Drugs Ordinance* (Cap. 23) or the *Customs Act* 2005; and

   e. the applicant is otherwise a fit and proper person to hold the licence.

6) Subject to the following provisions, the Committee may at any time cancel, suspend or vary a license, either with immediate effect or from such date as specified by the Committee.

7) The cancellation, suspension or variation may of a licence under this section may be complete or may be limited, including to medicines of one or more descriptions or at particular premises.

8) The Committee may exercise its powers under subsection 6 if satisfied that:

   a. the matters stated in the application on which the licence was granted were false or incomplete in a material particular;

   b. the premises of the licence holder are unsuitable for the display, assembly, storage or sale of medicines;

   c. the licence holder has breached a licence condition;

d. the licence holder requests in writing that the licence be cancelled, suspended or varied;

e. medicines to which the licence relates can no longer be regarded as products which can safely be administered for the purposes indicated in the licence;

f. the licence holder ceases to carry on the medical business or profession to which the licence relates;

g. the holder of the licence holder has without reasonable excuse failed to comply with a requirement imposed on the holder under this Part to provide information to the Committee;

h. the licence holder or a body corporate currently or previously controlled by the applicant (directly or indirectly) has been convicted of an offence against this Act, *Medical Services Act* 1996, the *Pharmacy and Poisons Ordinance* (Cap. 70), the *Dangerous Drugs Ordinance* (Cap. 23) or the *Customs Act* 2005; or

i. the applicable fees have not been paid within 28 days of becoming payable.

9) Where the Committee proposes to refuse, cancel, suspend or vary a licence, or to grant a licence otherwise than in accordance with the application, the Committee shall, unless it considers that to do otherwise would create an imminent risk of death, serious illness or injury, give the applicant or licence holder:

a. written notice of the proposed decision of the Committee; and

b. an opportunity within 14 days to make submissions to the Committee in relation to the proposed decision.

10)The Committee shall take any submissions made in accordance with subsection 5(b) into account before making a decision relating to the refusal, cancellation, suspension or variation of a licence.

23. Application for a review

1) Any applicant or licence holder who is aggrieved by an order made by the Committee may appeal to the Minister in writing within 14 days from the date of the order.

2) The Minister shall consult within the Ministry and may direct the Committee to rescind, suspend, vary, modify, or reconsider the order against which the appeal has been lodged.

24. Register of medicine license holders

1) The Committee shall maintain a register of medicine licence holders, which shall list the licence holders authorised to deal with medicines and the applicable conditions and restrictions applying to the respective licences.

2) On a decision to grant, cancel, suspend or vary a licence under section 22 taking effect, the Committee shall update the list.

25. Clinical Trials

Any person who manufactures, imports, prescribes, compounds, stores, distributes or supplies any medicine for the purposes of a clinical trial, unless such trial is authorised by regulations under this Act, commits an offence.

## PART 5 – PHARMACOVIGILANCE

26. Duty to report adverse effects

1) If at any time any importer, manufacturer or supplier of medicines or a person who administers medicines has reason to believe that a substantial adverse reaction has arisen from the use of the medicine (whether in Kiribati or elsewhere), the person must immediately notify the Committee of the nature of those effects and the circumstances in which they have arisen, so far as they are known to that person.

2) Any person who fails to provide information required under this section commits an offence and is liable on conviction to a fine not exceeding $2000.

## PART 6 – LABELLING, PACKAGING, AND PROMOTION

27. Clear labelling and packaging requirement

1) All dispensed medicines must be clearly labelled and packaged to ensure that medicines are correctly described and readily identifiable and their safe use is promoted.

2) Regulations made under this Act may prescribe requirements for labels, packages, advertisements or may prohibit certain advertisements.

3) Particular advertisements may be approved by the Committee in writing.

4) A medicine that is not labelled or packaged, or not labelled or packaged as required by the regulations made under this Act or with written approval of the Committee, shall be deemed to be labelled or packaged contrary to subsection 1.

5) Any person that publishes, or arranges for any other person to publish, any advertisement for a medicine in Kiribati, unless such advertisement is authorised by regulations under this Act, commits an offence.

6) Any person that labels, packages, sells or advertises a medicine in a manner that is false, misleading or deceptive as regards its character, constitution, value, potency, quality, composition, merits or safety, commits an offence.

## PART 7 – POWERS OF COMMITTEE

28. General powers

The Committee has the powers to do all things necessary or convenient to be done for, or in connection with the performance of its functions under this Act.

29. Powers of entry, search, inspection and seizure

1) For the purpose of discharging his or her functions under the legislation, an authorised officer may at any reasonable time enter and inspect any place, premises or vehicle which the authorised officer reasonably suspects to be used for or in connection with the manufacture, import, export, preparation, storage, distribution or supply of any medicine and:

    a. take samples of any medicine or of any substance relating to a medicine;

    b. examine records or other documents relating to any medicine;

    c. take photographs;

d. make any enquiries as is considered necessary to assist the exercise of any function or power under this Act; and

e. seize without payment any medicine or other substance, article or document which he or she has reasonable cause to believe to be a substance, article or document in which or by means of which an offence under this Act is being or has been committed.

2) On demand by any person in any premises or vehicle, or claiming any interest in any seized property, in or in respect of which any power is exercised under this section, the authorised officer shall identify himself or herself and produce evidence of his position as an authorised officer.

3) Subsection 1 does not authorise forcible entry by an authorised officer to any premises except under the authority of a warrant.

4) Where any property is seized pursuant to subsection 1, the Committee may decide to detain or store the seized property at any place it thinks fit until released or disposed of under this Act.

5) If the Committee after investigation is satisfied that there has not been a contravention of any of the provisions of this Act, the seized property will be returned to the person from they were seized.

6) If the Committee is satisfied that there has been a contravention of any of the provisions of this Act, it may retain the property for as long as is necessary for those purposes, and thereafter dispose of it with the consent of the owner of the property or the person previously in possession of the property person, or otherwise deal with the property as the Court may direct.

30. Power to obtain information

1) In relation to any matter relevant to the operation or enforcement of this Act, an authorised officer or the Committee may, by written notice served on a person, require a person (either by oral or written requisition) to provide any information or records within such time and in such format as specified in the notice.

2) A person who fails to provide the information required under this section without reasonable cause commits an offence and shall be liable on conviction to a fine not exceeding $1000.

31. Direction to secure compliance

1) If any provision of this Act has not been complied with, the Committee or 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) A person to whom a direction is issued under this section and who does not comply with the direction commits an offence.

## PART 8 – GENERAL OFFENCES AND PENALTIES

32. General Offences

1) Any person who manufactures, imports, exports, prescribes, compounds, stores, distributes or supplies a medicine that -

    a. is unfit for use in humans;

    b. is adulterated;

    c. has upon it any natural or added deleterious substance which renders it injurious to health; or

    d. has been manufactured, prepared, preserved, packaged or stored for sale under insanitary and/or unfavourable conditions,

    commits an offence.

2) Any person who manufactures, imports, exports, prescribes, compounds, stores, distributes or supplies any medicine which is a counterfeit or is known or suspected to be a counterfeit commits an offence.

3) Where a standard is prescribed in regulations for any medicine, any person who labels, packages, sells, offers for sale, distributes or promotes a medicine which does not conform to such standard in such manner as is likely to be mistaken for the medicine for which the standard has been prescribed commits an offence.

4) Where a standard has not been prescribed for a medicine, but a standard for the medicine is contained in any of the following publications -

    a. the European Pharmacopoeia;

    b. the British Pharmacopoeia;

    c. the British Pharmaceutical Codex;

    d. the United States Pharmacopoeia;

    e. the United States National Formulary; or

    f. the Therapeutic Goods Standards of Australia, then

    no person shall label, package, sell or advertise any substance in such a manner that it is likely to be mistaken for that medicine, unless the substance complies with the standard contained in that publication.

5) Any person who supplies any medicine by means of an automatic vending machine, except as may be permitted by regulations made under this Act, commits an offence.

6) Any person who knowingly make or aids and assists in a false or misleading statement or representation either:

    a. orally or in writing to the Committee or any authorised officer engaged in the exercise of its powers under this Act; or

    b. in an application for inclusion of a medicine on the Register of Medicines or for a licence under this Act

commits an offence.

7) Any person who -

a. wilfully obstructs an authorised officer acting in pursuance of this Act and duly authorised so to act by the Committee by -

i. assaulting, abusing or intimidating the authorised officer;

ii. directly or indirectly deliberately preventing any person from being questioned by the authorised officer;

iii. refusing to allow an authorised officer to take any medicine or related material that the authorised officer reasonably requires;

iv. removing, altering or interfering with any property seized under this Act; or

v. in any other way hindering or attempting to hinder the authorised officer;

b. wilfully fails to comply with any requirement properly made to him or her by a person so acting under section 30 of this Act; or

c. without reasonable cause fails to give to a person so acting any other assistance or information which that person may reasonably require of him of her for the purpose of the performance of his functions under this Act,

commits an offence.

33. Penalties

A person who contravenes or fails to comply with any provision of this Act creating an offence is liable on conviction, where there is no penalty provided, to -

a. in the case of a first offence for an individual, a fine not exceeding $2000 and imprisonment for a term not exceeding 12 months;

b. in the case of a second offence or subsequent offences, a fine not exceeding $5000 and imprisonment for a term not exceeding 24 months; and

c. in the case of a body corporate, a fine not exceeding $5000 for a first offence and $10,000 for a second or subsequent offences.

## PART 9 – MISCELLANEOUS PROVISIONS

34. Offences by corporate bodies

If a body corporate commits an offence against this Act, every person who is a board member or director or is otherwise concerned in the management of the body also commits the offence as an individual, unless the person proves:

a. that the offence was committed without his/her consent or knowledge; and

b. that he/she exercised reasonable diligence to prevent the commission of the offence, having regard to the nature of his or her functions in the corporate body and to all circumstances.

35. Additional powers of the Court

1) If a person is convicted of an offence under this Act, the court, in addition to any other penalty, may order:

a. if a person is convicted under section 32(7), that the seized property be destroyed by an authorised officer and that the person shall pay the reasonable costs incurred in confiscating and destroying the property

b. that a person's licence under this Act be cancelled.

2) Costs payable under subsection 1 may be recovered in the same way as a fine.

36. Regulations

1) The Minister, acting in accordance with the advice of the Cabinet and after consultation with the Committee, may make regulations under this Act prescribing all matters required or permitted by this Act to be prescribed or necessary or convenient to give effect to this Act.

2) Without limiting subsection 1 or affecting any other regulation-making power in this Act, regulations made by the Minister may prescribe:

a. the application fees in respect of applications under this Act;

b. the manner and form of an application for inclusion of a new medicine on the Register of Medicines or an application for any licence under this Act;

c. conditions applying to licence classes and medicine registrations under this Act;

d. standards for medicines;

e. information requirements for medicine labels and packages; or

f. requirements or prohibitions relating to medicine advertisements or clinical trials.

## Part 10 – REPEAL, CONSEQUENTIAL AMENDMENTS AND TRANSITIONAL PROVISIONS

37. The *Pharmacy and Poisons Ordinance (Cap. 70)* and regulations made under that Ordinance are hereby repealed.

38. Amendment to the *Value Added Tax Act* 2013

1) This section amends the *Value Added Tax Act* 2013.

2) Schedule 2 of that Act is amended by repealing the definition of 'medicine' and substituting the following definition –

'medicine' has the same meaning as the expression 'medicine' in section 4 of this Act.

39. Relationship with the *Dangerous Drugs Ordinance* (Cap. 23)

1) In the case of a medicine that is a dangerous drug within the meaning of the *Dangerous Drugs Ordinance* (Cap. 23); the prohibitions, conditions, and requirements contained in or imposed under this Act shall be in addition to the prohibitions, conditions, and requirements contained in or imposed under that Act to the extent that they are not inconsistent.

2) Nothing in the *Dangerous Drugs Ordinance* (Cap. 23) shall authorise any person to prescribe, manufacture, pack, label, sell by wholesale or retail, administer, procure, receive, store, use, or otherwise have in that person's possession any medicine contrary to the provisions of this Act.

40. Transitional Provisions

1) Every person who, immediately before the commencement of Part 4 of this Act, held a Medicine Licence under the *Pharmacy and Poisons Ordinance* (Cap.70) shall be deemed to be licensed to sell the medicines listed on the licence until the date on which the licence would have expired if that Act had not been repealed.

2) Section 17(1) of this Act shall not have effect in relation to a person who prescribes, compounds, stores, distributes or supplies medicines if the medicines were imported or procured for supply or distribution with the approval of Ministry at any time before the date of commencement of this Act.

# EXPLANATORY MEMORANDUM

## Introduction

A sustainable and effective pharmaceutical system is crucial for protecting and promoting public health in Kiribati. To this end, sound medicinal regulation is essential to establish a legal framework which ensures that only quality, safe and effective medicines enter the supply system. Medicines need to be regulated, as consumers are not equipped to independently assess their efficacy, safety, and quality.

Regulation is particularly important in the current context of the growing need for essential medicines due to the expanding burden of diseases and the ever-increasing complexity of a sophisticated pharmaceutical sector in which private actors have more and more involvement, a phenomenon which can be observed in Kiribati. While the increased role for the private sector has the potential to improve health service provision by facilitating increased medicinal options for the public, it is important that government regulation of the sector evolves correspondingly to assume a more prominent role.

The medicinal regulation provisions within the current *Pharmacy and Poisons Ordinance* (Cap. 70) have been in force since 1949. The provisions, being outdated and cumbersome to administer, have been superseded by current practice which is at odds with this legislation. In addition, many standard aspects of medicinal regulation are not contained in the ordinance.

This Act seeks to regulate medicines by: establishing a regulatory authority, the Medicinal and Therapeutics Committee, to regulate the importation, supply and distribution of medicines; introducing appropriate controls and standards in dealings with medicines; establishing legal requirements to ensure that medicinal information is accurate; and implementing strong enforcement mechanisms. Effective coordination is assured through the establishment of a central regulatory body with overall responsibility and accountability for all aspects of medicine regulation.

This Act is designed to better meet the needs of Kiribati's modern health care system. It has been drafted to be appropriate to the context of Kiribati, for example in creating a system where marketing authorisation (registration) for medicines can be based upon assessments made by a foreign medicine regulation authority (such as through the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce). It is in keeping with international practice for medicines to be regulated through a distinct piece of legislation, which is why a new act is being introduced rather than the *Pharmacy and Poisons Ordinance* (Cap.70) being revised. This Act is comprehensively drafted to cover all areas of pharmaceutical activity in Kiribati.

The Act will enable Kiribati to better regulate medicines in the country and improve public health. It creates a legislative framework which is in tune with the existing situation and national medicine policy and which, through dedicating specific areas of application for regulations to be issued, is also sufficiently flexible and dynamic. In this way, the legislation and regulations work together to achieve their objective. As knowledge about medicines is continually evolving, with new information on indications, side effects, and interactions with other medicines being constantly discovered, medicine registration and licensing must be a dynamic process, to align with continual inevitable developments in the pharmaceutical sector.

## Part 1 – Preliminary

Part 1 begins with three standard provisions: short title, commencement, and the binding of the Government.

Section 4 of the Act provides definitions of certain words and expressions used in the Act.

Section 5 makes it clear that the Act applies to everyone in Kiribati, including the Government and public servants and the private sector while Section 6 sets out the objects of the Act.

Part 2 – The Medicines and Therapeutics Committee

Section 7 establishes the Medicine and Therapeutics Committee, the committee with designated responsibility to monitor and regulate all medicines in Kiribati. The functions of the Committee are listed in section 8, and its composition, structure and the conduct of its meetings is provided for in section 9.

Part 3 – The Register of Medicines

Part 3 creates a system of approving and registering medicines for use in Kiribati. The Committee has the power to declare particular substances to be medicines (section 10) and is required to maintain two lists which together form the Register of Medicines: the Kiribati Essential Medicines List and the Kiribati List of Other Registered Medicines (section 11). Having the Committee maintain these list, and not including a prescriptive list of medicines in the legislation itself, will help to ensure that the legislation is able to remain current and flexible as new medicines are created and introduced.

The Committee classifies every medicine according to a Medicine Schedule in order to stipulate how the medicine is to be made available to the public (section 13). New medicines may be added to the list by the Committee or by application (section 13) which the Committee considers in light of prescribed criteria (section 14).

The Committee has the power to cancel, suspend or vary the registration of a particular medicine (section 15) and there are avenues for reviews against this decision, establishing an administrative safeguard (section 16).

Part 4 – Controls on dealing with medicines

Any dealings with medicine are prohibited unless the medicine is registered and the person has an appropriate licence or authority (section 17). The licence provision is a notable departure from the current framework set out in the ordinance, through which only pharmacists are able to import or supply medicines. Providing for licensing for others to be able to deal with medicine, particularly importers or suppliers, will facilitate greater access to medicines while ensuring that the Committee has oversight and regulatory control over such medicines.

Particular health professionals are authorised to prescribe certain medicines in line with the restrictions in the Medicine Schedule (section 18) and similarly, authorities for supplying, dispensing and administering medicines is in line with the Medicine Schedule is set out in the Act (section 19). There is specific provision for licenced retail outlets to be able to sell Level 1 medicines; while a similar provision exists in the current ordinance, the list of substances which they may sell do not include any modern 'over the counter' medicines which should be easily accessible to the public. Linking the authority back to the Medicine Register and Medicine Schedule will allow the Act to keep up to date with current medicinal developments.

Certain exemptions apply to the licence or authority requirement. These relate to personal use, needs of a particular patient or during a public health emergency, and donations made to Kiribati (section 20).

The application process for licences is contained in section 21, and the Committee has the power to grant, refuse, cancel or suspend a licence, in accordance to listed criteria, and to impose additional conditions (section 22).

There are options for review rights against licence decisions (section 23). The Committee will maintain a register of licence holders (section 24) and any clinical trials are prohibited unless

regulations specifically authorise it (section 25). This protects the people of Kiribati from unauthorised clinical trials but also allows for possible clinical trials to take place in the future, should new developments arise.

Part 5 – Pharmacovigilance

There are currently no legal requirements to facilitate reports of adverse drug reactions, and section 26 accordingly establishes such a requirement.

Part 6 – Labelling, Packaging, and Promotion

All dispensed medicines must be clearly labelled and packaged (section 27). Any false or misleading promotion or advertisement of medicines is prohibited, and all advertisements are prohibited, although there is scope for regulations to allow for advertisements should future developments warrant (section 27).

Part 7 – Powers of Committee

The Committee has general powers in order to perform its functions under the Act (section 28) as well as specific powers of entry, search, inspection and seizure (section 29). It may obtain information by written notice (section 30) and make directions to secure compliance with the Act (section 31).

Part 8 – General Offences and Penalties

General offences relating to medicines are set out in section 32, including in respect of adulterated, or counterfeit or substandard medicines, sale by vending machines, the making of false statements or obstruction of an authorised person. Penalties (where not provided elsewhere) are set out in section 33.

Part 9 – Miscellaneous Provisions

Part 9 deals with miscellaneous matters, including offences by corporate bodies (section 34), the powers of the court (section 35), the power of the Minister to make regulations (section 36).

Part 10 – Repeal, Consequential Amendments and Transitional Provisions

The *Pharmacy and Poisons Ordinance* (Cap. 70) and the regulations under that ordinance are repealed (sections 38) and amendments made to references in the *Value Added Tax Act* 2013 is noted in section 39. This new Act ensures that there is just one regulatory system applicable to pharmacists.

The relationship with the *Dangerous Drugs Ordinance* (Cap. 23) is clarified (section 39).

Transitional provisions are set out in section 40: while it is highly unlikely that any licences exist under the ordinance, this section protects the rights of any such licence-holders. In addition, any person who deals with medicines which were imported or procured with the approval of the Ministry of Health and Medical Services before the commencement date of the Act will not be deemed to have committed an offence.

## CERTIFICATE OF THE CLERK OF THE MANEABA NI MAUNGATABU

This printed impression of the Medicines Act 2018 has been carefully examined by me with the Bill which passed the Maneaba ni Maungatabu on the 23rd April 2018 and is found by me to be a true and correctly printed copy of the said Bill.

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**Eni Tekanene**
**Clerk of the Maneaba ni Maungatabu**

Published by exhibition at the Maneaba ni Maungatabu this ...13... day of .....02 Febel..... 2018.

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**Clerk of the Maneaba ni Maungatabu**