Ministry of Health (Pharmacy and Therapeutic Products) Regulations 2013

Tom Marsters **Queen's Representative**

Order in Executive Council

At Avarua, Rarotonga this 2nd day of October, 2013

Present:

His Excellency the Queen's Representative in Executive Council

Pursuant to section 39 of the Ministry of Health Act 2013, His Excellency the Queen's Representative, acting on the advice and with the consent of the Executive Council, makes the following regulations—

Contents

Regulations

1 Title

These regulations are the Ministry of Health (Pharmacy and Therapeutic Products) Regulations 2013.

2 Commencement

These regulations come into force on the day after the date on which these regulations are made.

3 Interpretation

In these Regulations, unless the context otherwise requires—

the Act means the Ministry of Health Act 2013

Administer means administer to a human being or animal, either—

(a) orally or by injection or by introduction into the body in any other way; or

(b) by external application, whether by direct contact with the body or not—

and every reference in these Regulations to administering a substance or article is a reference to administering it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some substance in which it is to be administered

Advertisement means an advertisement by any of the following means—

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

Analysis means the carrying out of tests capable of assessing the composition, strength, potency, sterility, purity, bio-burden, design, construction or performance characteristics of a therapeutic product

Animal means any animal (other than a human), whether vertebrate or invertebrate, and includes the semen, ova or embryo of an animal (other than a human) or any other substance or thing directly relevant to the reproduction of an animal (other than a human)

Authorised prescriber means a registered medical practitioner or other health professional authorised to prescribe medicines under these Regulations or any approved standards and codes of practice, and in the case of the prescription of medicines to animals, includes a veterinarian

Authorised officer means an officer appointed and empowered by the Act

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

Business includes—

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

Chief Pharmacist means the Chief Pharmacist of the Ministry of Health, or any person acting for the time being in such position

Conduct means any act or omission

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

Cosmetic means any substance or mixture of substances used or represented for use for the purpose of beautifying, improving, protecting, altering, or cleansing the hair, skin, or complexion of human beings; and includes—

(a) any perfume:
(b) any deodorant:
(c) any dusting powder

Dentist means a person who is duly registered as such under any applicable law in the Cook Islands

Dispensing in relation to a drug, means supplying that drug in accordance with a prescription given by a registered medical practitioner, a registered dentist, a veterinary practitioner or such other health practitioner as is authorised by law to prescribe medicines and therapeutic products

hospital pharmacy means a pharmacy located in and being part of a hospital, clinic or health facility operated or managed by the Ministry, or an Island Administration with the approval of the Ministry

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 the Customs in accordance with the Customs Act

Label includes any tag, brand, mark or statement in writing on or attached to or used in connection with any container or package containing any substance, material, body or thing referred to in these Regulations

Manufacture includes any process carried out in the course of making a product

Medical practitioner means a person who is duly registered as such under any applicable law in the Cook Islands

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

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

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

Midwife means a person who is duly registered as such under any applicable law in the Cook Islands

Minister means the Minister responsible for health

Nurse means a person who is duly registered as such under any applicable law in the Cook Islands, and includes a nurse practitioner

Package includes every means by which such substance, material, body or thing may, for transport or for carriage or for storage or for supply, be cased, covered, enclosed, contained or packed

Pharmacist means a person who is duly registered as such under these Regulations

"Pharmacist only" medicine means any medicine specified as such in the Cook Islands Medicines Schedule

"Pharmacy only" medicine means any medicine specified as such in the Cook Islands Medicines Schedule

Pharmacy means the facility or premises used for the practice of pharmacy, or for any business deemed to be a pharmacy under any approved standards or codes of practice

Pharmacy assistant means a person who performs tasks relevant to the practice of pharmacy but who is not registered as a pharmacist of pharmacy technician

Pharmacy Board and **the Board** means the Board established under regulation 4(1)

Pharmacy technician means a person who undertakes any practice of pharmacy, other than dispensing a drug or operating or supervising a pharmacy, and is not a registered pharmacist

Practice of pharmacy means—

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

Prescription means the written order in an approved form and issued by an authorised prescriber for the supply of a medicine or poison to any person

Prescription medicine means any medicine specified as such in the Cook Islands Medicines Schedule

Professional misconduct, in relation to a pharmacist or pharmacy technician, includes all of the following—

(a) any conduct that demonstrates a lack of adequate knowledge, skill, judgment or care:
(b) any act or omission—
    (i) contravening a provision of the Act (or any standard, code practice or other requirement applying under the Act), or these Regulations:
    (ii) contravening a registration condition imposed by the Board:
    (iii) contravening an order made or a direction given by the Board:
    (iv) being under a disability or subject to a medical condition which materially affects their practice:
(c) any other improper or unethical conduct relating to the practice of pharmacy

Recognised registration body means a registration body recognised by the Board, whose decisions are recognised for the purpose of ensuring that pharmacists and pharmacy technicians hold the appropriate qualifications and possess the requisite level of experience to allow them to safely practice in the Cook Islands

Recognised regulator means a therapeutic products regulator recognised by the Head of Ministry by written determination, as having the capacity and resources to determine whether therapeutic products are safe and effective

Register means the register of pharmacists, the register of pharmacy technicians or the register of licensed pharmacies (as the case may be), and any other register maintained in accordance with these Regulations

Registrar means the person designated by the Head of Ministry under regulation 4(7) to be the Registrar for the purposes of these Regulations

Sell includes—

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

and sale has a corresponding meaning

Standing Order means a written instruction issued by an authorised prescriber, in accordance with any applicable regulations, authorising any specified class of persons engaged in the delivery of health services to supply and administer any specified class or description of prescription medicines or controlled drugs to any specified class of persons, in circumstances specified in the instruction, without a prescription

Substance includes preparation or admixture and all salts and derivatives of any substance

Supply means any of the following—

(a) to sell or to agree to sell:
(b) to offer for sale or advertise for sale:
(c) to expose, transmit, convey, deliver, make or prepare for sale:
(d) to hire, exchange or dispose of for any consideration:
(e) to transmit, convey or deliver pursuant to a sale, exchange or disposal:
(f) to have in possession for any purpose referred to in this definition

Supply by wholesale, in relation to a substance or goods, means—

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

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

(i) in a public institution; or
(ii) in connection with the carrying on by persons, in circumstances required by these Regulations, of any activity so required

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

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

Therapeutic purpose means—

(a) treating or preventing disease; or
(b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or
(c) effecting contraception; or
(d) inducing anaesthesia; or
(e) altering the shape, structure, size, or weight of the human body; or
(f) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way; or
(g) cleaning, soaking, or lubricating contact lenses.

Part 1
The Pharmacy Board

4 The Pharmacy Board

(1) A Board to be called the Pharmacy Board is hereby established.

(2) The Board consists of the following members—
(a) the Head of Ministry, who is the Chairperson:
(b) the Chief Pharmacist:
(c) the Registrar:
(d) a medical practitioner nominated by the Cook Islands Medical Association:
(e) a representative of the private pharmacy profession appointed by the Minister; and
(f) a representative of the community appointed by the Minister.

(3) When holding an inquiry under Part 4, the Board may co-opt a legal practitioner to sit on the Board for the purpose of advising in relation to the proceedings of the inquiry and the powers of the Board.

(4) The members nominated or appointed under sub-regulation (2)(d), (e) and (f) hold office for a period of 2 years, and are eligible for re-appointment.

(5) The appointment of a member nominated or appointed under sub-regulation (2)(e) or (f) may be cancelled by the Minister, and another person may be nominated or appointed in place of such member for the remaining period of office.

(6) A member nominated or appointed under sub-regulation (2)(d), (e) or (f) may resign by giving notice of such resignation to the Minister, and another person may be nominated or appointed in place of such member for the remaining period of office.

(7) The Head of Ministry is authorised to appoint a Registrar to perform the duties of the Registrar of the Board, and to perform any other function or duty required by the Board or the Head of Ministry.

(8) The seal of the Board must be kept in the custody of the Registrar and is to be affixed by the Registrar or any other officer duly authorised by the Board to seal documents on behalf of the Board.

(9) The Board must prepare an annual report of its activities during the preceding 12 months, and this report must be made to the Minister.

5 Meetings of the Board

(1) Meetings of the Board may be convened by the Head of Ministry at any time, and a meeting must be convened if the Head of Ministry is requested to do so by at least one-half of the members of the Board.

(2) At any meeting of the Board at least one-half of the members of Board constitute a quorum.

(3) At every meeting of the Board the Chairperson has a deliberative vote and, in the case of an equality of votes, the Chairperson also has a casting vote.

(4) Subject to sub-regulation (3), every question before a meeting of the Board is to be determined by a majority of votes of the members present at the meeting.

(5) Except as otherwise provided in these Regulations, and any law relating to the regulation of health professions, the Board may regulate its procedures as it thinks fit.

(6) The Board is required to report to the Minister when the Minister requires it to do so.

(7) Any member of the Board who has a material conflict of interest concerning a matter before the Board must declare that conflict and take no part in the Board's deliberations on that matter.

Part 2
Regulation of pharmacists and allied pharmacy professionals

6 Functions of the Board in relation to the registration of pharmacy professionals

The functions of the Board in relation to the registration and regulation of pharmacy professionals include all of the following—

(a) to administer the procedures applying to the registration and discipline of pharmacists, and the practice of the pharmacy profession as provided for by these Regulations and any law relating to the regulation of health professionals:

(b) to determine the qualifications and experience necessary for registration as a pharmacist:

(c) to determine any qualifications and experience necessary for a pharmacist to be in private practice:

(d) to determine the requirements for continuing education to be undertaken by registered persons:

(e) to determine the professional standards applying to pharmacists and other registered pharmacy professionals, and the practice of pharmacy in the Cook Islands:

(f) to bring the professional standards to the attention of registered persons in any manner that the Board thinks fit:

(g) to assist the Registrar to effectively monitor and enforce the approved professional standards and notify the Registrar of suspected breaches so that investigations can be undertaken:
(h) to advise the Ministry and other Government agencies in relation to matters related to the effective regulation of the pharmacy profession and to the practice of pharmacy:
(i) to assist the Ministry to develop, monitor and enforce policies relevant to the practice of pharmacy so as to promote and protect the health of the community:
(j) to develop and implement arrangements for the regulation of pharmacy assistants and pharmacy technicians, and for the promotion of their work within the profession:
(k) to determine certain professional rights of registered pharmacists and other registered pharmacy professionals relevant to the performance of their practice of pharmacy:
(l) to assist in the resolution of disputes which may arise between or amongst pharmacists and other registered pharmacy professionals.

7 Professional standards to be determined by the Board

(1) The Board has authority to do all of the following—
(a) to determine the professional standards to be observed by pharmacists:
(b) to determine any specific professional standards to apply to pharmacists in private practice or working for pharmacies managed by the Ministry:
(c) to determine matters relevant to the registration and responsibilities of pharmacy assistants and pharmacy technicians, and the supervision of their work by pharmacists:
(d) to ensure that the professional standards approved under this regulation—
(i) are consistent with the proper and effective administration and operation of hospitals and the provision of medical and pharmaceutical services to the public:
(ii) reflect matters of Government policy and administrative practice relating to the provision of medical and pharmaceutical services as advised from time to time by the Ministry; and
(iii) ensure that the medical and pharmaceutical services provided to all persons in Cook Islands meet accepted international standards and are consistent with the human rights applying to all persons in Cook Islands:
(e) to review the approved professional standards, and make necessary amendments to them—
(i) at least once every calendar year; and
(ii) when a specific request to do so is made by the Head of Ministry:
(f) to liaise with the Head of Ministry when professional standards are being determined or changed to ensure that the requirements of paragraph (d) are met:
(g) to notify the Ministry of the approved professional standards, or the changes to them:
(h) to take appropriate action to monitor and enforce the professional standards in accordance with the requirements of these Regulations.

(2) The Board may adopt the professional standards applying to pharmacists, pharmacy assistants and pharmacy technicians in any other country as the professional standards to be observed by those classes of pharmacy professionals in the Cook Islands.

(3) In the absence of any professional standards determined and applied under this regulation, the standards set from time to time by the International Pharmaceutical Federation in relation to pharmacists and pharmacy technicians are applied to the respective pharmacy professionals.

(4) The Board may establish a committee to deal with matters relevant to professional standards, and may delegate to that committee any of its functions, powers and responsibilities concerning professional standards.

(5) Nothing in this regulation affects any relevant guideline, standard or code of practice approved and applied under the authority of the Act, and any such guidelines, standards or codes of practice must be applied and enforced by the Board insofar as they relate to the pharmacy profession and the practice of pharmacy.

8 Professional standards applying to other healthcare professionals to be taken into account

The Board must ensure that the professional standards determined under regulation 7, and by other Boards relating to the work of healthcare professionals, take account of the role of other healthcare professionals affecting the work and duties of pharmacists, pharmacy assistants and pharmacy technicians.

9 Qualifications for registration as a pharmacist

(1) To be eligible for registration as a pharmacist, a person must either—

(a) hold a degree in pharmaceutical chemistry from an educational institution recognised by the Board as providing acceptable courses of instruction for the purpose of maintaining the standards applying to pharmacists in Cook Islands; or

(b) hold a certificate or diploma as a pharmaceutical chemist granted in any country and which is recognised by the Board as being sufficient to ensure that the holder of the certificate or diploma is able to attain the professional standards applying to pharmacists in Cook Islands.

(2) In addition to the qualifications required under sub-regulation (1), for a person to be registered as a pharmacist, he or she must meet all of the following criteria—

(a) must have undertaken such practical experience in the practice of pharmacy as the Board may require:

(b) must be at least 21 years of age:

(c) must be of good character and reputation.

(3) The Board may defer any decision until the applicant provides sufficient details or verification of any of the following—

(a) the course or courses undertaken by the applicant for the obtaining of the relevant degree, certificate or diploma and the academic record of the applicant:

(b) any required practical experience in the practice of pharmacy:

(c) any matter relevant to the applicant undertaking private practice or working for the Ministry:

(d) any current registration to practice pharmacy in Cook Islands or elsewhere held by the applicant:
(e) any current eligibility for the practice of pharmacy held by the applicant, including compliance with any requirement to undertake continuing education:
(f) the identity, age, character and repute of the applicant; and
(g) any disciplinary action taken against the applicant as a pharmacist in Cook Islands or elsewhere.

10 Procedures of the Board

The provisions of the Ministry of Health (Health Professionals Registration and Discipline) Regulations 2013 apply to all procedures of the Board relevant to any function or power given to the Board under these Regulations.

Part 3
Licensing of pharmacy premises

11 Pharmacies to be licensed

(1) The practice of pharmacy, or the operation of a pharmacy business, may only be carried out on premises which are approved and licensed under these Regulations.
(2) This regulation does not apply to hospital pharmacies operated by the Ministry of Health.
(3) A person who carries on the practice of pharmacy, or who operates a pharmacy business, in premises which are not licensed under this Part commits an offence and is liable upon conviction to a fine not exceeding $10,000, and $1,000 for every day that the offence continues.

12 Register of Licensed Pharmacy Premises

(1) For the purposes of these Regulations, a register of licensed pharmacy premises and businesses must be maintained in accordance with any requirements determined by the Head of Ministry, and such registry must contain particulars of approved premises, and the owners or operators of them.
(2) The register may be kept by electronic means.

13 Applications for licences

(1) Every application for a licence must be made to the Head of Ministry in the approved form, and each application must be referred to the Board for consideration.
(2) Every such application must contain or be accompanied by such particulars, information, documents, and other material as may be required by the Head of Ministry or the Board, and must be accompanied by the fee determined in accordance with the Act.

14 Criteria to be satisfied by pharmacy operators

(1) The Head of Ministry must not grant an application for a licence to operate a pharmacy on any premises unless the Board is satisfied in respect of all the following matters—
(a) the requirements of this Part have been complied with:
(b) the applicant is a fit and proper person to hold the licence applied for:

(c) every person proposed to be responsible for managing the licensed premises and business has a sufficient knowledge of the obligations of a licensee under these Regulations, and of the hazards associated with the therapeutic products in which it is proposed to deal:

(d) the premises and all associated equipment that the applicant proposes to use are suitable and adequate, and comply with all applicable standards and codes of practice, and any other requirements imposed by the Board from time to time:

(e) adequate arrangements have been made or are to be made for the making, maintaining, and safekeeping of adequate records in respect of therapeutic products that are imported, manufactured, stored, packed, labelled, sold or supplied in accordance with the licence.

(2) If the Head of Ministry intends to decline an application for a licence under this Part the applicant must be given a reasonable opportunity to be heard.

15 Further information may be required

(1) The Head of Ministry may require an applicant for a licence under this Part to supply additional information to that provided in the application, or to verify any information supplied in support of an application.

(2) If the applicant fails to supply the information requested within 20 days of the date of the request, or within any further time allowed by the Board, the application lapses.

16 Conditions of licence to operate a pharmacy

(1) It is a condition of every licence issued under this Part that—

(a) the pharmacy must be operated under the supervision and control of a registered pharmacist who is the holder of a current practising certificate:

(b) no prescription medicine or other class of therapeutic product determined from time to time in accordance with these Regulations, may be dispensed or supplied by a person other than a registered pharmacist who is the holder of a current practising certificate:

(c) the holder of the licence must not request or require any pharmacist or other person who is employed or engaged in duties at a pharmacy to act in a way that is inconsistent with the applicable professional or ethical standards of pharmacy practice:

(d) every person who is responsible for managing the pharmacy must ensure that every prescription medicine or restricted medicine in the pharmacy is at all times secured in a way that prevents the public gaining ready access to the medicine:

(e) A system of Quality Assurance consistent with all applicable standards and codes of practice must be applied to the pharmacy business or practice.

(2) The Board may impose any further conditions on any licence issued under this Part.

(3) Sub-regulation (1)(d) does not prevent a pharmacist engaged at the pharmacy, or another person authorised by a pharmacist engaged at the pharmacy, from supplying any medicine to a member of the public.

(4) The requirements imposed by sub-regulation (1)(c) and (d) are in addition to the requirements imposed by any guidelines, standards or codes of practice applied to pharmacies under the Act.

(5) A person who breaches any condition under this regulation or any other applicable condition applied to a licence, commits an offence and is liable upon conviction to a fine not exceeding $15,000.

17 Application procedures for approval of pharmacy premises

(1) A licence-holder must seek approval for new pharmacy premises, or for additions or alterations to existing pharmacy premises, from the Pharmacy Board.

(2) Application for approval of pharmacy premises should be made to the Pharmacy Board as follows -

(a) the appropriate application form approved by the Pharmacy Board should be completed and forwarded to the Pharmacy Board together with plans of the premises:

(b) the application should be forwarded to the Pharmacy Board with at least one months notice.

(3) When the Pharmacy Board has considered the plans and has advised that it agrees to the plan 'in principle, the applicant should proceed to construct the premises as agreed to by the Pharmacy Board.

(4) When the premises have been completed in accordance with the application, the Pharmacy Board must be advised.

(5) The Pharmacy Board will arrange for the premises to be inspected as soon as practicable after receipt of the advice of completion.

(6) If upon inspection, the premises are found to be in accord with the agreed plans, the Pharmacy Board will formally approve the premises.

(7) If, upon inspection, the premises are found not to be in accord with the agreed plans, the Pharmacy Board may require the applicant to make alterations.

18 Certain publications to be kept

(1) Any person carrying on the practice of pharmacy, or who is responsible for managing a pharmacy business, must keep a copy these Regulations, together with a recent edition of Martindale - The Extra Pharmacopoeia (and all published amendments and supplements) on the premises at all times.

(2) The requirements imposed by sub-regulation (1) are in addition to the requirements imposed by any guidelines, standards or codes of practice applied under the Act.

(3) A person who fails to keep the publications required under this regulation on the premises, commits an offence and is liable upon conviction to a fine not exceeding $500.

19 Licence to be issued and displayed

(1) No sign may be displayed on any premises using the title or word "pharmacy" or any similar title, sign or designation, unless the premises have been licensed as a pharmacy under this Part.

(2) If premises are licensed under this Part and upon payment of the applicable fee, a licence in the approved form will be issued, and must be prominently displayed at all times at the premises.

(3) A person who contravenes any requirements under this regulation commits an offence and is liable upon conviction to a fine not exceeding $1,000.

20 Cancellation or suspension of a licence

(1) The Board may cancel or suspend a licence issued under this Part on the following grounds—

(a) a pharmacy is no longer operated on the premises to which the licence relates:

(b) the pharmacy business has operated in breach of the provisions of these Regulations, or any requirements applying to them under the Act, or any other law.

(2) Before cancelling or suspending the licence, the Board must cause a notice to be served on the owner or manager of the pharmacy, requiring that cause be shown, within such time as is specified in the notice, as to why the licence should not be cancelled or suspended.

(3) If no cause is shown within the time stipulated in the notice referred to in sub-regulation (2), or if cause is shown but the Board is not satisfied with it, the Board may cancel or suspend the licence.

(4) An Order of the Board under sub-regulation (3) take effect from such date as is specified in the Order.

Part 4
Regulation of therapeutic products

21 Functions of the Board in relation to therapeutic products

(1) The functions of the Board in relation to the regulation of therapeutic products include all of the following—

(a) to develop and implement the Cook Islands National Medicines Policy, comprising strategies to achieve the following objects—

(i) to ensure the long term access and availability of effective and safe essential medicines at an affordable cost:

(ii) to promote the rational, sound and cost effective use of medicines by health professionals and the public:

(b) to monitor and evaluate the implementation of the Cook Islands National Medicines Policy, and make any revisions that are needed to the Policy:

(c) to advise the Minister and the Ministry on matters associated with the regulation of therapeutic products in the Cook Islands:

(d) to advise the Head of Ministry in relation to the following—

(i) developing, maintaining, and publishing the Cook Islands Medicines Schedule, which will list all the medicines or classes of medicines that are approved for use in the Cook Islands, and medicines and classes of medicines that are not so approved:

(ii) determining and applying relevant guidelines, standards and codes of conduct under the Act:

(e) to maintain, keep up to date, and publish the Cook Islands Essential Medicines List in accordance with the National Medicines Policy:

(f) to determine the product range and determine the therapeutic products to be purchased by the Ministry based on the Cook Islands Essential Medicines List:

(g) to advise the Minister and the Ministry on the scheduling or classification of medicines for the purposes of the Act:

(h) to provide advice on the development of Standard Treatment Guidelines, education or training programmes, or other initiatives for health professionals who use the medicines on the Cook Islands Essential Medicines List:

(i) to establish, at its discretion, a database to record and monitor drug side effects and reactions based upon reports which must be provided by health professionals.

(2) The Board may establish a sub-committee so as to more effectively discharge any of its functions under this Part, and may delegate to the sub-committee any of its functions or powers.

(3) The Board may co-opt qualified pharmacists and any other appropriate person to serve on the Board or a sub-committee established under sub-regulation (2), for such term and for such purposes as it thinks fit.

22 Scheduling of medicines

(1) The Head of Ministry has authority to approve, maintain, publish, apply and enforce the Cook Islands Medicines Schedule, specifying medicines which can be imported into and used in the Cook Islands, and those which are prohibited from importation, sale and use.

(2) The Head of Ministry, on the advice of the Board, may determine the classes of medicines for the purpose of the Cook Islands Medicines Schedule.

(3) In deciding if a given medicine or class of medicines should be added to the Cook Islands Medicines Schedule as an approved medicine, the Head of Ministry must consider all of the following features and characteristics of each medicine—

(a) its usefulness to the people of the Cook Islands:

(b) its demonstrated efficacy:

(c) its safety profile:

(d) its quality:

(e) its registration or approval status with recognised regulators.

(4) The Head of Ministry must cause the Cook Islands Medicines Schedule to be reviewed annually, and may amend any of the medicines or classes in the Cook Islands Medicines Schedule by written determination.

(5) The Cook Islands Medicines Schedule may recognise and reference the approved medicines lists of other countries.

(6) The Cook Islands Medicines Schedule may be kept in electronic format.

(7) The Ministry must make the Cook Islands Medicines Schedule, including any medicines lists referenced under sub-regulation (5), readily available to the pharmacy profession and the public.

Part 5
Controls on dealings with therapeutic products

23 Importation and supply of therapeutic products

(1) No person may import, manufacture, sell, supply or promote any therapeutic product unless that product has been approved by a recognised regulator and is on the Cook Islands Medicine Schedule as an approved product.

(2) For the purpose of sub-regulation (1), a person who wishes to import, manufacture, sell, supply or promote any therapeutic product must hold documentation sufficient to satisfy the Head of Ministry that the product has been approved by a recognised regulator.

(3) If a recognised regulator has granted an approval subject to conditions, those conditions apply to any supply or promotion of the product in the Cook Islands, unless those conditions are modified by the Head of Ministry, acting on the advice of the Board.

(4) Upon application by a registered medical practitioner, pharmacist or veterinarian, the Head of Ministry may authorise the importation of a therapeutic product which has not been approved by a recognised regulator, in order to meet the particular treatment needs of an individual patient or animal.

(5) The Head of Ministry may authorise the importation of a medicine not approved by a recognised regulator in the interest of public health during a major disaster or period of emergency.

(6) The giving of an authorisation under sub-regulations (3), (4) or (5) does not render the Crown, the Ministry of Health or any person acting in accordance with these Regulations, liable in respect of any loss, damage or injury of any kind suffered as a result of, or arising out of, the use of therapeutic products by any person or animal.

(7) Nothing in this regulation prevents the importation by any person of a medicine if that importation is for personal therapeutic use which is evidenced by a letter or certificate of that person's medical practitioner registered outside the Cook Islands, or is for the purpose of a clinical trial authorised by the Ministry.

(8) Any person who contravenes any provision of this regulation commits an offence and is liable upon conviction to a fine not exceeding $10,000, or to imprisonment not exceeding 12 months, or both.

24 Control of therapeutic products available in the Cook Islands

(1) If there is any reason to believe that any therapeutic product may be unsafe or ineffective for the therapeutic purpose for which it is used or intended for use, the Head of Ministry may, by notice in writing to an importer, manufacturer, wholesaler or seller, require the importer, manufacturer, wholesaler or seller to satisfy the Ministry or the Board as to the safety or efficacy of that product.

(2) If the Head of Ministry is not satisfied, by evidence supplied pursuant to a notice under sub-regulation (1) or otherwise, of the safety and efficacy of a therapeutic product to which the notice relates, the Head of the Ministry may, by notice in writing to the importer, manufacturer, wholesaler or seller—

(a) prohibit the importation, manufacture, distribution or sale of that product in the Cook Islands either indefinitely or for such period as may be specified in the notice; or

(b) impose such conditions as may be specified in the notice on the importation, manufacture, distribution, advertising, packaging, sale or supply of the product.

(3) The Head of Ministry may at any time by notice, revoke any notice given under sub-regulation (2), or vary, revoke, or add to any conditions imposed in any such notice.

(4) The Head of Ministry may order the recall of a therapeutic product by giving notice to an importer, manufacturer or other person supplying the product, if the quality, safety or efficacy of the product becomes unacceptable to the Head of Ministry; or where the importer or manufacturer or other person supplying the product has failed to comply with a condition to which the Therapeutic Product is subject.

(5) A person who fails to comply with a notice issued by the Head of Ministry under this regulation, or any condition stated in such a notice, commits an offence and is liable upon conviction to a fine not exceeding $10,000, or to imprisonment not exceeding 12 months, or both.

25 Powers to prohibit import or supply of therapeutic products

(1) The Minister may, by notice delivered to any person or published by any means determined by the Minister, prohibit the import, manufacture, packing, sale, possession, supply, or use of therapeutic products of any specified description, either absolutely or subject to such conditions as the Minister thinks fit.

(2) If the Minister gives a notice under sub-regulation (1), he or she must, on the written request of any person, state the reasons for doing so.

(3) A person who fails to comply with a notice issued under this regulation, or any condition stated in such a notice, commits an offence and is liable upon conviction to a fine not exceeding $10,000, or to imprisonment not exceeding 12 months, or both.

26 Controls over donated medicines

Donated medicines may be imported into the Cook Islands only if all of the following are met—

(a) they have been approved by an approved regulator:

(b) they are of known good quality:

(c) they are labelled with the generic international non-proprietary name (INN):

(d) they, if sent under the same program or to the same recipient regularly, are of consistent strength and quality:

(e) they meet the specifications required under the Act, these Regulations, or the Chief Pharmacist:

(f) the prospective donations are fully detailed and approved by the Chief Pharmacist before dispatch of the donation from the home port:

(g) they have a "use by" or "expiry" date provided with sufficient useful life remaining after the estimated arrival date in the Cook Islands:

(h) the donation complies in all other respects with the World Health Organization Guidelines for Drug Donation.

27 Retail sale of medicines

(1) The following requirements apply to the sale of medicines by retail, or to their supply in circumstances corresponding to retail sale, or to their distribution by way of gift or loan or sample, or in any other way—

(a) if the medicine is a prescription medicine it—

(i) must be sold, supplied, or distributed by a registered pharmacist in a licensed pharmacy or from a hospital pharmacy, strictly in accordance with the prescription applying to its supply; or

(ii) supplied in accordance with a standing order by a person who is authorised to supply and administer any specified class or description of prescription medicine under that standing order; or

(b) if the medicine is a "pharmacist only medicine" it must be sold, supplied, or distributed by a registered pharmacist in a licensed pharmacy or a hospital pharmacy:

(c) if the medicine is a "pharmacy only medicine" it must be sold, supplied, or distributed in a licensed pharmacy or a hospital pharmacy.

(2) No person may sell or supply, any prescription medicine otherwise than—

(a) under a prescription given by an authorised prescriber; or

(b) in accordance with a standing order.

(3) No person is permitted to sell any therapeutic product by means of an automatic vending machine or by auctioning the product, unless he or she has approval from the Head of Ministry.

(4) A person who breaches sub-regulation (1), (2) or (3) commits an offence and is liable upon conviction to a fine not exceeding $10,000, or to imprisonment not exceeding 12 months, or both.

28 Administering prescription medicines

(1) No person is permitted to administer any prescription medicine to any other person otherwise than strictly in accordance with the directions of the authorised prescriber who prescribed the medicine.

(2) A person who breaches this regulation commits an offence and is liable upon conviction to a fine not exceeding $5,000, or to imprisonment not exceeding 12 months, or both.

29 Supply of medicines from hospital pharmacies

(1) The Head of Ministry may approve any arrangements and procedures for the supply of medicines (by sale or otherwise) from hospital pharmacies, and such arrangements apply despite any other provision of these Regulations.

(2) Health professionals may be authorised to supply or dispense therapeutic products on behalf of the Ministry in accordance with any authority given by the Head of Ministry, subject to any conditions or restrictions imposed from time to time by the Head of Ministry.

30 Advertising of therapeutic products prohibited

(1) No person is permitted to publish, or arrange for any other person to publish, any advertisement for a therapeutic product in the Cook Islands, unless such advertisement is authorised by any regulations or by an approved standard or code of practice.

(2) A person who breaches this regulation commits an offence and is liable upon conviction to a fine not exceeding $5,000, or to imprisonment not exceeding 6 months, or both.

31 Storage of therapeutic products

(1) Any person who—

(a) is in possession or control of any therapeutic product for the purposes of its sale or supply; or

(b) is in possession of any container or appliance used for or in connection with—

(i) the sale of any therapeutic product; or
(ii) the manufacture, storage, or packing of any therapeutic product for sale—

must at all times store the product safely and in accordance with any requirements set out in relevant guidelines, standards and codes of practice applied under the Act, any requirements applying under these Regulations or any direction given by the Head of Ministry or the Chief Pharmacist.

(2) A person who breaches this regulation commits an offence and is liable upon conviction to a fine not exceeding $5,000, or to imprisonment not exceeding 6 months, or both.

32 Duty to report untoward effects of medicines

(1) If at any time the importer, manufacturer or supplier of any therapeutic product has reason to believe that any substantial untoward effects have arisen from the use of the medicine (whether in the Cook Islands or elsewhere), the importer, manufacturer or supplier must immediately notify the Head of Ministry in writing of the nature of those effects and the circumstances in which they have arisen, so far as they are known to that person.

(2) A person who breaches this regulation commits an offence and is liable upon conviction to a fine not exceeding $5,000.

33 Duty to have and produce specifications of therapeutic products

(1) No person is permitted to—
(a) sell, supply or distribute by way of gift or loan, or sample or in any other way; or
(b) advertise for sale; or
(c) advertise the availability of—
any therapeutic product, unless that person is in possession of details of the specifications for testing the quality of that product.

(2) Every person to whom this regulation applies must, on demand, supply to an authorised officer the details and certificates referred to in sub-regulation (1).

(3) A person who breaches this regulation commits an offence and is liable upon conviction to a fine not exceeding $5,000, or to imprisonment not exceeding 6 months, or both.

34 Restrictions on prescribing and supplying to individuals

(1) The Head of Ministry may issue a Restriction Notice if he or she has reason to believe that an individual—
(a) is addicted or habituated to a medicine; and
(b) is likely to seek further supplies of, or prescriptions for, that medicine.

(2) A Restriction Notice may provide for—
(a) exceptions to the restrictions stated in the Notice, including an exception allowing certain specified persons to prescribe or supply the specified medicine to the restricted individual in certain circumstances, specified quantities, or both; or
(b) any other conditions the Head of Ministry determines.

(3) The Head of Ministry may revoke or modify a Restriction Notice by issuing a further Notice.

(4) The Head of Ministry must serve a copy of a Restriction Notice, or further Notice on the restricted individual, but a failure to do so does not invalidate the Notice, or affect the responsibility of persons to comply with it.

(5) A Restriction Notice restricts—

(a) prescribers from prescribing the medicine specified in the Notice to the restricted individual named in the Notice; and

(b) persons from supplying the medicine specified in the Notice to the restricted individual named in the Notice.

35 Prescribing or supplying in contravention of a restriction notice

(1) A person must not prescribe or supply medicines to a restricted individual in contravention of a restriction notice issued under regulation 34.

(2) A person who knows, or who ought reasonably to have known, that the person prescribed or supplied medicines in breach of this regulation is a restricted individual commits an offence and is liable, on conviction—

(a) in the case of an individual - to a fine not exceeding $10,000 or a term of imprisonment not exceeding 3 months, or both; or

(b) in the case of a body corporate - to a fine not exceeding $40,000.

Clerk of the Executive Council

These regulations are administered by the Ministry of Health.

These regulations were made on the 2nd day of October 2013
