THERAPEUTIC GOODS ACT

Chapter 28.34

2016 Revised Edition

Tonga

THERAPEUTIC GOODS ACT

Arrangement of Sections

Section

THERAPEUTIC GOODS ACT

AN ACT TO ESTABLISH A SYSTEM OF REGULATION OF THERAPEUTIC GOODS, TO ESTABLISH A NATIONAL DRUGS AND MEDICAL SUPPLIES COMMITTEE, TO REGULATE THE IMPORT, QUALITY, AVAILABILITY AND USE OF REGISTERED THERAPEUTIC GOODS, INCLUDING NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES AND FOR ANCILLARY PURPOSES[1]

Commencement [1st July 2010[2]]

PART I - PRELIMINARY

1 Short title and commencement

This Act may be cited as the Therapeutic Goods Act, and shall come into force on a date to be proclaimed by His Majesty in Council, and different Parts may be brought into force on different dates.

2 Interpretation

In this Act, unless the context otherwise requires —

"**advertisement**" means an advertisement —

(a) published in a newspaper, magazine or other publication;

(b) placed in a circular, handbill, poster or other notice;

(c) made orally or by any means of producing light or sound;

(d) made using a form of electronic communication or utilising an application of information technology, including an advertisement placed on the internet; or

(e) made in any other manner;

"**analysis**", in relation of therapeutic goods, means the carrying out of tests capable of assessing the composition, strength, potency, sterility, purity, bioburden, design, construction or performance characteristics of the goods;

"**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);

"**assistant pharmacist**" means a person who is duly registered as such under the Pharmacy Act;[3]

"**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;

"**Central Pharmacy and Medical Store**" means the Central Pharmacy and Medical Store of the Ministry of Health;

"**Committee**" means the National Drugs and Medical Supplies Committee established under Part II of this Act;

"**conduct**" means any act or omission;

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

"**counterfeit drug**" means a drug which is deliberately and fraudulently mislabelled with respect to identity or source;

"**customs officer**" means an officer appointed under the Customs and Excise Act;[4]

"**dental therapist**" means a person who is duly registered as such under the Medical and Dental Practice Act;[5]

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

"**generic medicinal drug**" means any multi-source medicinal drug not being the originator brand;

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

"**herbal medicine**" means a medicine consisting of a substance produced by subjecting a plant to drying, crushing or other process, or a mixture of such substances, with or without inert ingredients;

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

"**licence**" means a licence issued and in force for the purposes of this Act or regulations made hereunder;

"**manufacture**" includes the process of refining, manipulating or mixing any medicinal drug (including a medicinal drug in the raw state);

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

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

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

(b) influencing, modifying or inhibiting 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,

but not a product the principal use of which is cosmetic;

"**midwife**" means a person who is duly registered as such under the Nurses Act;[6]

"**Minister**" means the Minister of Health;

"**narcotic drugs and psychotropic substances**" means substances, whether natural or synthetic, listed in the United Nations Single Convention of Narcotic Drugs 1961 and in the United Nations Convention on Psychotropic Substances 1971;

"**National Health Development Committee**" means the National Health Development Committee of the Ministry of Health;

"**new medicinal drug**" means a medicinal drug which is not presently registered in the Kingdom;

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

"**nurse practitioner**" means a person duly registered as such under the Nurses Act;[7]

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

"**pharmacist**" means a person who is duly registered as such under the Pharmacy Act;[8]

"**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 of 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 operating relates to the practice of pharmacy; and

(h) supervising the practice of pharmacy;

"**premises**" includes ships, aircraft and vehicles;

"**prescription**" means the written order of a dentist, dental officer, health officer or medical practitioner for the supply of a medicinal drug to any person or the written order of a veterinary practitioner for the supply of a medicinal drug to any animal;

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

"**registered list**" means the Tongan Registered List of Medicinal Drugs under Part III of this Act;

"**selling**" includes sale by wholesale or retail and barter and exchange, and also includes dealing in, agreeing to sell, or offering or exposing 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 or things;

"**special prescription**" means the written order of a medical practitioner predominantly practising in a particular recognized special area for the supply of a medicinal drug for therapeutic use by a person being treated for a condition under that special area;

"**substance**" includes preparation or admixture and all salts and derivatives of any substance;

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

"**supply by wholesale**", in relation to a substance or goods, means —

(a) supply of the substance or goods for the purposes of re-supply; or

(b) supply of an ingredient for the purposes of incorporation in the substance or goods,

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

(c) in a public institution; or

(d) in connection with the carrying on by persons, in circumstances required by this Act or the regulations, of any activity so required;

"**therapeutic devices**" means therapeutic 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 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;

"**therapeutic goods**" includes —

(a) medicinal drugs and products;

(b) herbal medicines other than those prepared by traditional Tongan healers;

(c) therapeutic devices;

(d) goods for use as an ingredient in the manufacturer of medicinal products and therapeutic devices; and

(e) goods for use as a container or part of a container for goods referred to in paragraphs (a), (b) and (d),

but not products the principal use of which is cosmetic;

"**veterinary practitioner**" means a person qualified to practice as a veterinary practitioner or veterinary surgeon in a jurisdiction outside the Kingdom who practises as a veterinary practitioner within the Kingdom.

3 Crown to be bound

This Act binds the Crown.

PART II - THE NATIONAL DRUGS AND MEDICAL SUPPLIES COMMITTEE

4 Establishment, functions and constitution of Committee

(1) There shall be established for the purposes of this Act a committee to be called the National Drugs and Medical Supplies Committee.

(2) The functions of the Committee shall be —

(a) to establish, maintain and annually revise and amend the list of medicinal drugs registered for import into the Kingdom;

(b) to determine the class in the registered list to which any medicinal drug will be allocated;

(c) to maintain, annually revise and amend a List of Essential Drugs for the Kingdom which shall be the basis for public sector medicinal drug procurement;

(d) to consider the product range and determine the therapeutic goods to be purchased by the Ministry of Health based on the List of Essential Drugs for the Kingdom;

(e) to confirm or reject decisions of the Principal Pharmacist regarding the award of tenders for the supply of therapeutic goods;

(f) to control procedures for the procurement, storage, distribution and administration of therapeutic goods;

(g) to receive from the Central Pharmacy and Medical Store, collate, review and, if necessary, suggest action, upon reports of adverse drug reactions within the Kingdom;

(h) to initiate, maintain and supervise a national programme on rational use of medicinal drugs;

(i) to advise the National Health Development Committee on any matter relating to the National Drug Policy; and

(j) to propose to the National Health Development Committee any changes or modifications to this Act, any Schedule hereto, or the National Drug Policy as may be deemed appropriate.

(3) The Committee shall consist of the following members —

(a) the Chief Executive Officer for Health;[9]

(b) the Principal Pharmacist;

(c) the Pharmacist in Charge, Vaiola Hospital;

(d) the Medical Superintendent, Vaiola Hospital;

(e) one nominee of the Tonga Medical Association;

(f) one nominee of the Tonga Nurses Association;

(g) two medical officers employed by the Ministry of Health designated by the Minister on the nomination of the medical officers of the Kingdom;

(h) one health officer designated by the Minister on the nomination of the health officers of the Kingdom;

(i) Matron of Vaiola Hospital; and

(j) one nominee from the Dental Division of the Ministry of Health designated by the Minister on the nomination of the Dental Division.

(4) The members designated by the Minister under subsections (3)(g), (h) and (j) shall hold office for a period of two years and shall be eligible for renomination.

(5) The nomination of any member may be cancelled by the body that nominated such person, and another person may be nominated in place of such member for the remaining period of office.

(6) Any nominated member may resign by giving notice of such resignation to the body that made the nomination, and such body may nominate another person for the remaining period of office.

(7) The Committee may co-opt one pharmacist in private practice and one medicinal drugs wholesaler to serve on the Committee for such term and for such purposes as it thinks fit.

(8) The Chief Executive Officer for Health shall be the chairman of the Committee.[10]

(9) The Principal Pharmacist shall be the secretary of the Committee.

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

(11) The Committee shall meet as required and shall report to the National Health Development Committee by way of provision of the Minutes of its meetings.

(12) The Committee shall prepare annually a report of its activities during the preceding 12 months and this report shall be made to the Minister.

(13) An act in good faith, by the Minister, chairman, secretary or any Committee member shall not subject that person to any liability.

PART III - TONGAN REGISTERED LIST OF MEDICINAL DRUGS

5 Establishment of registered list

(1) The Committee shall maintain a registered list, to be known as the Tongan Registered List of Medicinal Drugs, specifying those medicinal drugs which may be imported into the Kingdom.

(2) The registered list shall contain the following classes —

Class 1: Medicinal drugs available from licensed retail outlets;

Class 2: Medicinal drugs available from registered pharmacy premises under the supervision of a registered pharmacist, divided into —

Class 2A: Where advice of pharmacist at point of sale is not required;

Class 2B: Where advice of pharmacist at point of sale is required;

Class 3: Medicinal drugs available on prescription only and dispensed by a pharmacist or assistant pharmacist;

Class 4: Medicinal drugs available on special prescription only and dispensed by a pharmacist or assistant pharmacist;

Class 5: Narcotic drugs and psychotropic substances subject to special import controls;

Class 6: Medicinal drugs available from veterinary practitioners for animal use.

(3) The Committee shall annually review the content of the registered list and may amend any of the classes of the registered list and give notice in the Gazette.

(4) The registered list may be kept in electronic format.

6 Advice as to content of registered list

The registered list shall record the medicinal drugs both by brand name and International Non-propriety Name (INN) and shall include the place of manufacture.

7 Criteria for inclusion in the registered list

A medicinal drug may be included in the registered list only if the Committee is satisfied that the medicinal drug —

(a) is of acceptable quality;

(b) meets an acceptable safety profile;

(c) is of demonstrated efficacy;

(d) is of United States Pharmacopoeia or British Pharmacopoeia standard or proven equivalent standard;

(e) has been proven by the manufacturer to be registered in one of the countries listed in the Schedule or following assessment of a detailed submission by the manufacturer, and payment of the prescribed fee, is found to meet the requirements of subsections (1) to (4); and

(f) would be appropriate for use in Tonga.

8 Application for inclusion in registered list

(1) Before any new medicinal drug is imported or offered for sale, the manufacturer of the medicinal drug or the licensed importer shall make an application to the Committee for —

(a) inclusion of the medicinal drug in the registered list; and

(b) allocation to the class of the registered list in which it is to be included.

(2) Any application for inclusion shall be made in the manner and form specified by the Committee and shall be accompanied by —

(a) the specified fee;

(b) a World Health Organization Certificate for a Pharmaceutical Product Moving in International Commerce, in the prescribed format and signed by the government regulatory authority in a country which is a signatory to the World Health Organization Certification Scheme, the country being that in which the manufacture has occurred, so long as the medicinal drug has been registered for sale on the local market in the country of manufacture; and

(c) any other documentation required under the power contained within subsection (3).

(3)

(a) The secretary of the Committee may, by notice in writing given to the applicant, require the applicant to give the Committee, within such reasonable time as is specified in the notice, such information specified in the notice concerning the composition, storage, indications, directions for use or labelling of the medicinal drug, advertising material relating to the medicinal drug, reports of adverse drug reactions or concerning treatment of over-dosage.

(b) A notice under paragraph (a) may require the information to be given —

(i) in writing; or

(ii) in accordance with specified software requirements on a specified kind of data processing device or by way of a specified kind of electronic transmission.

(4) Notwithstanding the requirement in subsection (2)(b) the Committee may define the information required and the format of submission for a medicinal drug for which inclusion on the registered list is desired and for which the documentation specified in subsection (2)(b) is not available.

(5) The Committee shall notify the applicant, in writing, of the Committee's determination and, if necessary, add the new medicinal drug to the registered list in the appropriate class.

(6) The decision of the Committee under this section is final.

9 Removal from registered list

The Committee may remove a medicinal drug from the registered list if —

(a) the importer or manufacturer requests in writing the removal from the registered list;

(b) the quality, safety or efficacy of the medicinal drug becomes unacceptable to the Committee;

(c) the importer or manufacturer has failed to comply with a condition to which the inclusion of the medicinal drug on the registered list is subject; or

(d) the registration fee is not paid.

PART IV - IMPORT, EXPORT, MANUFACTURE AND QUALITY CONTROL OF THERAPEUTIC GOODS

10 Import of medicinal drugs

(1) Any person who imports, distributes, prescribes or offers for sale a medicinal drug which is not included in the registered list commits an offence.

(2) A person may not import, manufacture, or sell by wholesale or retail any medicinal drug unless licensed to do so under this Act.

(3) Upon application by a registered medical practitioner or pharmacist, the Minister may authorise the importation of a medicinal drug not included in the registered list in order to meet the particular treatment needs of an individual patient.

(4) The Minister may authorise the importation of a medicinal drug not included in the registered list in the interest of public health during a major disaster or period of emergency.

(5) The giving of an authorisation under subsections (3) or (4) shall not render the Crown, 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 therapeutic goods by that person or another person.

(6) Nothing in this section prevents the importation by any person of a medicinal drug not included in the registered list when that importation is for personal therapeutic use which is evidenced by a letter or certificate of that person's medical practitioner registered outside the Kingdom or is for the purpose of an approved clinical trial.

11 Import licence

(1)

(a) An application for an import licence shall only be made by a pharmacist, veterinary practitioner, wholesaler or retailer.

(b) The import licence shall be limited to those therapeutic goods in the class of the registered list under section 5(2) authorised as able to be held by the applicant.

(2) The holder of an import licence shall not intentionally or recklessly breach a condition of the licence.

(3) An application for an import licence shall —

(a) be made in writing in the form prescribed in the regulations;

(b) identify the therapeutic goods that the applicant wishes to import and the class of the registered list in which they are included;

(c) be delivered to the Central Pharmacy and Medical Store; and

(d) be accompanied by the specified application fee.

(4) A person shall not, in or in connection with an application for a licence to import therapeutic goods, make a statement that is, to the person's knowledge, false or misleading in any material particular.

12 Granting of import licence

(1) The secretary of the Committee may, by notice in writing given to the applicant for an import licence, require the applicant —

(a) to give the Committee, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice; or

(b) to allow an authorised officer, at any reasonable time specified in the notice, to inspect the premises, equipment and facilities that will be used for the storage of the therapeutic goods included in the application for the import licence.

(2)

(a) Where a person has made an application to import therapeutic goods and the therapeutic goods are within the class of the registered list authorised to be held by the applicant; and

(i) the specified application fee has been paid;

(ii) any specified inspection fees have been paid; and

(iii) the person has complied with any requirements made by the Committee under subsection (1) in relation to the application,

the Committee shall grant the person a licence to import therapeutic goods of the applicable class of the registered list.

(b) Notwithstanding paragraph (a) if the Committee is satisfied that —

(i) the premises of the applicant, if a pharmacist, do not comply with the licensing or other requirements of the Pharmacy Act; or

(ii) the premises of the applicant, if a retail outlet, are not appropriate for the display, storage or sale of therapeutic goods;

(iii) the applicant has had an import licence granted to him revoked;

(iv) the applicant has been convicted of an offence against this Act, the Pharmacy Act or the Customs and Excise Act;

(v) the applicant controls a body corporate (whether directly, or indirectly through one or more interposed entities) that has been convicted of an offence against this Act, the Pharmacy Act or the Customs and Excise Act; or

(vi) the applicant controlled a body corporate (whether directly, or indirectly through one or more interposed entities) when the body committed an offence against this Act, the Pharmacy Act or the Customs and Excise Act, and the body has been convicted of any such offence or, where the applicant is a body corporate and is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has been convicted of any such offence,

the Committee shall refuse to grant an import licence.

(3) Where the Committee grants or refuses to grant an import licence, the Committee shall —

(a) give the applicant written notice of the decision; and

(b) in the case of a refusal, include in the notice reasons for the refusal.

(4) Where the Committee grants an import licence, the secretary to the Committee shall publish particulars of the decision in the Gazette as soon as is practicable.

(5) An import licence commences on the day specified in the licence and remains in force until it is revoked or suspended.

(6) An import licence may be granted subject to —

(i) conditions designed to ensure that the holder of the licence imports the therapeutic goods in accordance with any required standards for transport, storage, or display, including temperature standards and any required standards relating to security of the goods; and

(ii) such other conditions relating to the import of the therapeutic goods as the Committee deems appropriate.

(7) The Committee may, by notice in writing given to the holder of an import licence, impose new conditions on the licence or vary or remove existing conditions.

(8) The imposition or variation of a condition under subsection (7) shall take effect —

(i) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury, on the day on which the notice is given to the person; or

(ii) in any other case, on a day specified in the notice, being a day not earlier than 28 days after the notice is given to the person.

(9) In addition to any conditions imposed under subsection (6) or (7), each import licence is subject to the conditions that the holder of the import licence shall —

(i) ensure that the goods shall conform to any standard applicable to the goods; and

(ii) allow an authorised officer or customs officer to enter, at any reasonable time, the premises to which the goods are imported and, while on those premises to inspect those premises and any therapeutic goods stored thereon, and to take samples of such goods.

(10) Subject to subsection (11), the Committee may, by notice in writing given to the holder of an import licence, revoke the licence, or suspend the licence for a period specified in the notice if —

(i) the holder has been convicted of an offence against this Act, the Pharmacy Act, or the Customs and Excise Act;

(ii) the holder controls a body corporate (whether directly, or indirectly through one or more interposed entities) that has been convicted of an offence against this Act, the Pharmacy Act or the Customs and Excise Act;

(iii) the holder controlled a body corporate (whether directly, or indirectly through one or more interposed entities) when that body committed an offence against this Act, the Pharmacy Act or the Customs and Excise Act and the body has been convicted of such offence;

(iv) the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has been convicted of an offence against this Act, the Pharmacy Act or the Customs and Excise Act;

(v) the holder has breached a condition of the licence;

(vi) the holder requests in writing that the licence be revoked or suspended, as the case may be;

(vii) the holder ceases to carry on the business or profession to which the licence relates; or

(viii) the annual licensing charge, or any applicable prescribed inspection fees, have not been paid within 28 days after they become payable.

(11) Where the Committee proposes to revoke a licence or suspend a licence otherwise than at the request of the holder of the licence, the Committee shall, unless the Committee considers that failure to revoke or suspend the licence

immediately would create an imminent risk of death, serious illness or serious injury —

(i) by notice in writing given to the holder, inform the holder of the action that the Committee proposes to take and of the reasons for that proposed action; and

(ii) except where the proposed action is to be taken as a result of a failure to pay the annual licensing charge or an applicable prescribed inspection fee, give the holder an opportunity to make, within such reasonable time as is specified in the notice, submissions to the Committee in relation to the proposed action.

(12) Where the holder makes submissions in accordance with subsection (11), the Committee shall take into account the submissions before making a decision relating to the revocation or suspension of the licence.

(13) A licence may be revoked notwithstanding that the licence is suspended.

(14) Where a licence is suspended, the Committee may, by notice in writing given to the holder of the licence, cancel the suspension.

(15) Where the Committee revokes or suspends an import licence, the secretary of the Committee shall publish particulars of the decision in the Gazette as soon as is practicable.

(16) The Committee may, from time to time and in such manner as the Committee determines, publish a list of persons who are licensed to import therapeutic goods under this section, and the classes of the registered list to which the licences relate.

13 Offences

(1) A person shall not —

(a) import therapeutic goods into the Kingdom;

(b) export therapeutic goods from the Kingdom except under an authority given by the Minister or where the exportation by a person is for personal therapeutic use which is evidenced by a letter or certificate of that person's medical practitioner registered in the Kingdom;

(c) manufacture in the Kingdom therapeutic goods; or

(d) supply therapeutic goods in the Kingdom,

unless the goods are included in the registered list and if imported are imported under a licence under section 12 or the goods are the subject of an authorisation by the Minister under section 10.

(2) Where a customs officer seizes medicinal drugs under powers contained in the Customs and Excise Act, the Principal Pharmacist shall be advised of the seizure as soon as practicable thereafter.

14 Manufacture of therapeutic goods prohibited except under licence

(1) A person shall not, at premises in the Kingdom, manufacture or carry out a step in the manufacture of therapeutic goods for supply for use in humans unless —

(a) the goods are or the person is exempt by regulations in relation to the manufacture of the goods; or

(b) the person is the holder of a manufacturing licence that is in force and authorises the carrying out of that manufacture or step in the manufacture:

Provided that this subsection shall not apply to or in relation to therapeutic goods that are manufactured by a dentist, dental therapist or manufactured by —

(c) a pharmacist or assistant pharmacist on premises in which the practice of pharmacy is carried on; or

(d) a pharmacist or assistant pharmacist on premises of the Ministry of Health;

for sale or supply, otherwise than by wholesale, on or from those premises.

(2) A person who is the holder of a manufacturing licence shall not breach a condition of the licence.

(3) A person shall not, in or in connection with an application for a manufacturing licence, knowingly make a statement that is false or misleading in a material particular.

(4) The Committee may, from time to time, by notice in writing, determine principles to be observed in relation to —

(a) the standards to be maintained and the equipment to be used at premises used for the manufacture of therapeutic goods;

(b) procedures for quality assurance and quality control to be employed in the manufacture of therapeutic goods;

(c) the qualifications and experience required by persons employed in the manufacture of therapeutic goods;

(d) the manufacturing practices to be employed in the manufacture of therapeutic goods; or

(e) other matters relevant to the quality, safety and efficacy of therapeutic goods that are manufactured in the Kingdom;

and may include codes of good manufacturing practice.

(5) An application for a manufacturing licence shall —

(a) be made in writing in the form prescribed in the regulations;

(b) identify the therapeutic goods or classes of therapeutic goods that the applicant proposes to manufacture;

(c) identify the premises that will be used in the manufacture of those goods;

(d) identify the steps in the manufacture of those goods that the applicant proposes to carry out under the licence;

(e) state the names, qualifications and experience of the persons who are to have control of the production of the goods and of the quality control measures that are to be employed;

(f) be delivered to the Central Pharmacy and Medical Store; and

(g) be accompanied by the specified application fee.

(6) The Committee may, by notice in writing, require the applicant —

(a) to give to the Committee, within such reasonable time as is specified in the notice, such further information concerning the application as is specified in the notice; or

(b) to allow an authorised officer, at any reasonable time specified in the application, to inspect the premises, equipment, processes, goods and facilities that will be used in the manufacture of the goods.

(7)

(a) Where a person has made an application to carry out steps in the manufacture of therapeutic goods at particular manufacturing premises; and

(i) the required prescribed application fee has been paid;

(ii) any applicable inspection fees have been paid; and

(iii) the person has complied with any requirements made by the Committee under subsection (6) in relation to the application,

the Committee shall grant the person a licence to carry out those steps at those premises.

(b) Notwithstanding paragraph (a) if the Committee is satisfied that —

(i) the applicant will be unable to comply with the manufacturing principles;

(ii) the premises are not satisfactory for the manufacture of the goods;

(iii) the applicant has had a manufacturing licence granted to him revoked;

(iv) the applicant has been convicted of an offence against this Act;

(v) the applicant controls a body corporate (whether directly, or indirectly through one or more interposed entities) that has been convicted of an offence against this Act;

(vi) the applicant controlled a body corporate (whether directly, or indirectly through one or more interposed entities) when the body committed an offence against this Act, and the body has

been convicted of such offence, or where the applicant is a body corporate and is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has been convicted of an offence against this Act; or

(vii) the applicant has failed on more than one occasion to observe the manufacturing principles in connection with the manufacture of therapeutic goods,

the Committee shall refuse to grant a manufacturing licence.

(8) Where the Committee grants or refuses to grant a manufacturing licence, the Committee shall —

(a) give the applicant written notice of the decision; and

(b) in the case of a refusal, include in the notice the reasons for the refusal.

(9) Where the Committee grants a manufacturing licence, the secretary to the Committee shall publish particulars of the decision in the Gazette as soon as is practicable.

(10) A manufacturing licence commences on the day specified in the licence and remains in force until it is revoked or suspended.

(11) A manufacturing licence may be granted subject to —

(a) conditions designed to ensure that the holder of the licence manufactures the goods in accordance with the manufacturing principles, and any standards applicable to the goods; and

(b) such other conditions relating to the manufacture of the goods as the Committee thinks appropriate.

(12) The Committee may, by notice in writing, impose new conditions in the manufacturing licence or vary or remove existing conditions.

(13) The imposition or variation of a condition under subsection (12) shall take effect —

(a) if the notice states that the action is necessary to prevent imminent risk of death, serious illness or serious injury, on the day on which the notice is given to the person; or

(b) in any other case, on a day specified in the notice, being a day not earlier than 28 days after the notice is given to the person.

(14) In addition to any conditions imposed under subsection (11) or (12), every licence is subject to the conditions that the holder of the licence shall —

(a) ensure that the goods conform to any standard applicable to the goods;

(b) not manufacture a medicinal drug using any counterfeit starting materials or without taking reasonable measures to ensure that the starting materials used or employed in the manufacture of such medicinal drug are not counterfeit or of suspect quality;

(c) allow an authorised officer —

(i) to enter, at any reasonable time, the manufacturing premises to which the licence relates;

(ii) while on those premises, to inspect those premises, any therapeutic good manufactured thereat and any process relating to that manufacture, and to take samples of such goods and to take photographs of those premises, goods or processes; and

(iii) to question the holder or his employees at those premises about procedures carried out there;

(d) if requested to do so by an authorised officer —

(i) produce to the officer such documents relating to the manufacture of therapeutic goods at those premises as the officer requires and allow the officer to copy the documents; and

(ii) produce to the officer for examination any batch samples kept by the holder; and

(e) comply with such other conditions (if any) specified in the regulations.

(15) Subject to subsection (16), the Committee may, by notice in writing given to the holder of the licence, revoke the licence, or suspend the licence for a period specified in the notice, if —

(a) the holder has been convicted of an offence against this Act;

(b) the holder controls a body corporate (whether directly, or indirectly through one or more interposed entities) that has been convicted of an offence against this Act;

(c) the holder controlled a body corporate (whether directly, or indirectly through one or more interposed entities) when that body committed an offence against this Act and the body has been convicted of that offence or where the holder is a body corporate and the holder is controlled by another person (whether directly, or indirectly through one or more interposed entities) and that other person has been convicted of an offence against this Act;

(d) the holder has breached a condition of the licence;

(e) the holder has failed to observe the manufacturing principles in connection with the manufacture of therapeutic goods;

(f) the holder requests in writing that the licence be revoked or suspended;

(g) the holder ceases to carry on the business of manufacturing the goods to which the licence relates; or

(h) the annual licensing charge, or any applicable inspection fees, have not been paid within 28 days after they become payable.

(16) Where the Committee proposes to revoke a licence or suspend a licence otherwise than at the request of the holder of the licence, the Committee shall, unless the Committee considers that failure to revoke or suspend the licence

immediately would create an imminent risk of death, serious illness or serious injury —

(a) by notice in writing given to the holder, inform the holder of the action that the Committee proposes to take and of the reasons for that proposed action; and

(b) except where the proposed action is to be taken as a result of a failure to pay the annual licensing charge or an applicable inspection fee, give the holder an opportunity to make, within such reasonable time as is specified in the notice, submissions to the Committee in relation to the proposed action.

(17) Where the holder makes submissions in accordance with subsection (16), the Committee shall take into account the submissions before making a decision relating to the revocation or suspension of the licence.

(18) A licence may be revoked notwithstanding that the licence is suspended.

(19) Where a licence is suspended, the Committee may, by notice in writing given to the holder of the licence, cancel the suspension.

(20) Where the Committee revokes or suspends a manufacturing licence, the secretary of the Committee shall publish particulars of the decision in the Gazette as soon as is practicable.

(21) The Committee may, from time to time and in such manner as the Committee determines, publish a list of the persons who are licensed under this section, the classes of goods to which the licence relates, the steps of the manufacture that the licence authorises and the address of the manufacturing premises to which the licence relates.

15 Quality control

(1) No person shall manufacture, import, export, compound, store, sell, advertise or distribute a medicinal drug that —

(a) is unfit for use in humans or in animals;

(b) is adulterated;

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

(d) has been manufactured, prepared, preserved, packaged or stored for sale under insanitary or unfavourable conditions;

(e) has been labelled, packaged or advertised in a manner that is false, misleading, deceptive or likely to cause an erroneous impression regarding its source, character, value, quality, composition, potency, merit or safety;

(f) contains any counterfeit starting materials or is known to be counterfeit or suspected to be a counterfeit.

(2) Any person who, without reasonable excuse, contravenes subsection (1) commits an offence.

(3) For the purpose of investigation of any suspected offence under subsection (1), the Committee may nominate an organisation, body or person which the Committee considers to be competent and not directly or indirectly engaged in or connected with the manufacture or sale of medicinal drugs, to carry out analysis of medicinal drugs.

16 Donated medicinal drugs

Donated medicinal drugs may be imported into the Kingdom only if —

(a) they are in the List of Essential Drugs for the Kingdom;

(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 programme or to the same recipient regularly, are of consistent strength;

(e) they meet the specifications of the Central Pharmacy and Medical Store;

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

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

PART V - SPECIAL IMPORT CONTROLS FOR NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

17 Authority to import narcotic drugs and psychotropic substances

(1) The Minister is authorised to import all narcotic drugs under international control listed within the most recent edition of the Annex to the statistical forms ("Yellow List") and psychotropic substances under international control listed within the most recent edition of the Annex to the Annual Statistical Report ("Green List"), prepared by the International Narcotics Control Board of the United Nations.

(2) The authorisation of the Minister under subsection (1) may be delegated to the Principal Pharmacist.

PART VI - REGULATION OF SUPPLY OF REGISTERED DRUGS

18 Sale by wholesale prohibited except under licence

(1) A person who sells by wholesale therapeutic goods, or a class of therapeutic goods, to which this section applies commits an offence unless the sale by wholesale is authorised under a licence.

(2) The Committee, with the approval of the Minister, may by regulations specify therapeutic goods or classes to which this section applies.

19 Licensing of retailers

(1) Non-pharmacy, retail outlets may obtain, hold, store and sell medicinal drugs contained in Class 1 of the registered list, subject to holding a current retail licence.

(2) The obtaining, holding, storing, selling or offering for sale by a non pharmacy, retail, outlet, of medicinal drugs other than those contained within Class 1 of the registered list, or the holding, storing, selling or offering for sale of medicinal drugs without a retail licence is an offence.

(3) A person who supplies medicinal drugs after the expiry date stated on the drugs commits an offence.

20 Authority to write prescriptions

(1) Any accredited health officer may write prescriptions for medicinal drugs included in Classes 1 and 2 of the registered list, and may write prescriptions for medicinal drugs included in Class 3 of the registered list on the advice of a medical practitioner.

(2) Any dentist may write prescriptions for medicinal drugs included in Classes 1, 2 and 3 of the registered list when the particular medicinal drug is for therapeutic use in the practice of dentistry.

(2A) Any nurse practitioner may write prescriptions for medicinal drugs included in Classes 1 and 2 of the registered list, and may write prescriptions for medicinal drugs included in Class 3 of the registered list on the advice of a medical practitioner.[11]

(3) Any medical practitioner may write prescriptions for medicinal drugs included in Classes 1, 2, 3 and 5 of the registered list.

(4) Any medical practitioner predominantly practising in a particular recognised special area may write prescriptions for medicinal drugs included in Class 4

of the registered list, when the particular medicinal drug is for therapeutic use of a person being treated for a condition under that special area.

(5) Any veterinary practitioner may write prescriptions for medicinal drugs included in Class 6 of the registered list.

(6) No person may write a prescription for the supply of narcotic drugs or psychotropic substances for his own use.

21 Requirements for prescriptions

(1) Except in cases of emergency, a registered pharmacist or assistant pharmacist shall not dispense any prescription for the supply of medicinal drugs unless the prescription —

(a) is in writing and dated and signed with the usual signature of the person authorised to give it, specifies that person's professional address and the name and address of the person for whom the prescription is given;

(b) when given by a registered dentist is endorsed "For dental treatment only";

(c) when given by a veterinary practitioner is endorsed "For animal treatment only";

(d) is endorsed by a registered medical practitioner issuing it with a statement as to the number of times the prescription shall be dispensed;

(e) if containing an unusual or dangerous dose includes a statement by the person issuing it that the dose is intentionally prescribed;

(f) is written in terms and symbols such as are used in ordinary professional practice, and states the generic name of the medicinal drug:

Provided that, when the prescription is signed by a medical practitioner, health officer, nurse practitioner or dentist, it shall include the practitioner's registration number given under the Medical and Dental Practice Act.[12]

(2) Where, in any emergency case, a prescription is issued orally to any registered pharmacist or assistant pharmacist, the prescription shall be provided in writing to the pharmacist or assistant pharmacist within 24 hours by the person issuing it.

22 Dispensing requirements

(1) Except as provided in subsection (2), no person shall dispense a medicinal drug upon prescription unless he is a registered pharmacist or assistant pharmacist or an assistant under the direct personal supervision and control of a registered pharmacist or a veterinary practitioner.

(2) Nothing in subsection (1) shall prevent a registered medical practitioner, health officer, nurse practitioner or nurse from dispensing a starting dose out

of hours, or dispensing a prescription or supplying a medicinal drug within the limit of his accreditation where no registered pharmacy premises, registered pharmacist or assistant pharmacist are available within 10 kilometres.[13]

(3) In dispensing a prescription for a medicinal drug —

(a) the medicinal drug shall not be dispensed more than once on the same prescription, except where the prescription so directs, in which case the medicinal drug may be dispensed at such interval or intervals as are stated in the prescription;

(b) the prescription shall be marked with the date on which it is dispensed, and with the name and professional address of the person who dispenses it;

(c) the person who dispenses a prescription for the last occasion shall endorse the prescription with the word "Cancelled";

(d) no person shall dispense a prescription endorsed as "Cancelled" or which has, or appears to have, been written more than 3 months before its presentation;

(e) no person shall dispense a prescription if he has reason to believe that the prescription is not genuine;

(f) no person shall dispense a prescription which is illegible or defaced or which appears to have been altered; and

(g) where a registered pharmacist or assistant pharmacist suspects that a prescription has been forged or fraudulently issued, or does not bear the signature of a registered medical practitioner, health officer nurse practitioner or dentist, he shall, notwithstanding that it is not dispensed, retain the prescription and report his suspicion to the Principal Pharmacist as soon as practicable.

(4)

(a) Every pharmacist or assistant pharmacist shall record every prescription dispensed, compounded or made up by him in a prescription book, or by electronic means.

(b) The prescription book or electronic record shall include —

(i) a number relating to the relevant prescription only and the prescription number;

(ii) the name and address of the person for whose use the medicine or drug was dispensed or compounded.

(5) The prescription book or electronic record shall be kept at the place at which the medicine or drug is dispensed and shall at all reasonable times be produced when demanded by an authorised officer.

(6) All original prescriptions as they are dispensed shall be marked with the prescription number, filed in numerical order and retained by the person dispensing the prescription for 2 years from the date of dispensing.

(7) Any person, who without reasonable excuse, contravenes this section commits an offence.

23 Labels on containers

(1) Every registered pharmacist, assistant pharmacist, medical practitioner, nurse, nurse practitioner or health officer shall, before delivering or dispatching to any person, or the agent of that person, a container containing a medicinal drug dispensed or compounded by him, affix to the container immediately containing the medicinal drug a label on which appears clearly in the Tongan language —

(a) a printed address identifying clearly the pharmacy at which the medicinal drug was compounded or dispensed;

(b) the name of the person for whom the medicinal drug was compounded or dispensed;

(c) such identification of the contents as is required by subsection (2);

(d) the directions for use specified in the prescription from which the medicinal drug was compounded or dispensed; and

(e) an identification mark corresponding to the prescription number as appearing in the prescription book or electronic record. [14]

(2)

(a) The identification referred to in subsection 1(c) shall be by reference to the generic name of the medicinal drug in the latest current edition of the United States Pharmacopoeia or the British Pharmacopoeia.

(b) the label of the container containing a medicinal drug shall be marked with such additional precautionary labelling as is considered relevant by the dispensing pharmacist or assistant pharmacist.

(3) The contents of this section do not preclude the addition to the label of a statement in the English language as to all or any of the matters required.

(4) Any person who, without reasonable excuse, contravenes this section commits an offence.

PART VII - MISCELLANEOUS PROVISIONS

24 Authorised officer

(1) The Minister may, by notice in the Gazette, specify a person or persons as authorised officers for the purposes of this Act.

(2) An authorised officer shall, upon request, provide proof that he is an authorised officer.

25 Powers of entry, search and seizure

(1) For the purposes of this Act, an authorised officer may at all reasonable times —

(a) enter any premises where medicinal drugs are being kept for retail trade or for the practice of pharmacy;

(b) enter any place, premises or vehicle in respect of which he knows or reasonably suspects —

(i) is or are being used for the practice of pharmacy;

(ii) have been or are being or are likely to be used by any person in contravention of this Act;

(c) enter any premises where he knows or reasonably suspects that records are kept relating to the practice of pharmacy or relating to a contravention of this Act;

(d) in any premises entered by him —

(i) search for or examine medicinal drugs, articles, equipment or documents and may take possession of any medicinal drugs, articles, equipment or documents, or samples thereof, or make copies of or extracts from records relating to the practice of pharmacy or relating to any matter the subject of an investigation under this Act;

(ii) seize any medicinal drugs, articles, equipment, documents, or samples thereof, or container or package which he reasonably suspects to contain any medicinal drugs, articles or equipment;

(iii) open any room, place, container or package that he knows or reasonably suspects contains any medicinal drugs, articles or equipment;

(iv) question with respect to matters under this Act any person he finds thereon;

(e) make such inquiry and examination as he believes to be necessary or desirable to assist the discharge or exercise of any function or power under this Act or to ascertain whether any contravention of this Act has been, is being or is likely to be committed.

(2) Subsection (1) does not authorise forcible entry by an authorised officer to any premises except under the authority of a warrant obtained pursuant to subsection (4).

(3) Unless he has the permission of the occupier of a part of the premises if that part is used as a dwelling, an authorised officer shall not enter that part without a search warrant issued by a Magistrate.

(4) A Magistrate, if satisfied upon the information of an authorised officer that there is reasonable cause to suspect that any place has been, or is being, or is likely to be used in connection with a contravention of this Act, may issue a

search warrant directing the authorised officer to enter the place specified in the search warrant for the purpose of exercising the powers conferred on an authorised officer by this Act.

(5) A search warrant issued under this section is, for a period of one month from its issue, sufficient authority —

(a) to the authorised officer to whom it is directed and to all persons acting in aid of the officer to enter the place specified in the search warrant; and

(b) to the authorised officer to whom it is directed to exercise in respect of the place specified in the search warrant all the powers conferred on an authorised officer by this Act.

(6) For the purpose of gaining entry to any place an authorised officer may call in aid such persons as he considers necessary and such persons, while acting in aid of an authorised officer in the lawful exercise of a power of entry, shall have a like power of entry.

(7) If an authorised officer has taken possession of records or of other property for the purposes of this Act he may —

(a) in the case of records, retain them for as long as necessary for those purposes, but the person otherwise entitled to possession of the records, if he so requests, is entitled to be furnished as soon as practicable with a copy certified by the authorised officer to be a true copy and such a certified copy must be received in all courts and elsewhere as evidence of the matters contained in it as if it were the original;

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

26 Power to obtain information

(1) In relation to any matter relevant to the operation or enforcement of this Act, an authorised officer may require a person (either by oral or written requisition) to furnish —

(a) any information;

(b) any records or a copy thereof,

in the person's possession.

(2) For the purpose of subsection (1), a person is to be taken to be in possession of —

(a) information, if the person has the information or is entitled to have access to the information;

(b) records, if the person has them in his possession or under his control in any place, whether for his own use or benefit or for another's use or

benefit and although another person has the actual possession or custody of the records.

(3) A requisition made under subsection (1) may require that the information or records or copy thereof be furnished —

(a) to the authorised officer or another authorised officer or to an officer of a specified department of the Government;

(b) at the place the requisition is made or at another place;

(c) forthwith or at, by or within a time specified;

(d) in person, or by registered mail or in another manner specified;

(e) by means of, or accompanied by, verification in the form of an affidavit;

(f) in the case of information, orally or in writing.

(4) A person must not without reasonable cause —

(a) refuse or fail to furnish any information, records or copy as required under this section;

(b) in response to a requisition made under this section furnish information, records or copies that is or are false or misleading in a material particular.

(5) If a person records or stores any matter by means of a mechanical, electronic or other device, the duty imposed by this section to produce any records containing those matters is to be construed as including a duty to produce the matters in written form if that is demanded.

(6) The duty imposed by this section to produce a copy of any records is to be construed as a duty to produce a clear reproduction.

(7) An authorised officer may take notes or copies of or extracts from records or a copy of any records produced under this section.

(8) Any person who fails to furnish information required under this section commits an offence.

27 Continuing offence

If a person commits an offence by failing to furnish information required under section 26 or to produce any records or a copy of any records —

(a) the obligation to furnish the information or to produce the records or a copy of them, as the case may be, continues until the person complies with the requirement notwithstanding that in a particular case a time was specified at, by or within which compliance was required and that time has passed;

(b) the person commits a continuing offence in respect of each day after the day of conviction during which the failure to comply with the requisition continues;

(c) the person is liable to a fine not exceeding $100 for each day during which the offence continues; and

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

28 Obstruction

(1) A person shall not obstruct an authorised officer in the exercise of his powers under this Act.

(2) For the purposes of this Act, a person obstructs an authorised officer in the exercise of his powers under this Act if he —

(a) assaults, abuses, intimidates or insults the authorised officer or any other person assisting the authorised officer in the exercise of his powers under this Act;

(b) directly or indirectly deliberately prevents any person from being questioned by an authorised officer in the exercise of his powers under this Act; or

(c) in any way obstructs or attempts to obstruct an authorised officer in the exercise of his powers under this Act.

29 Directions may be issued to secure compliance

(1) If —

(a) any pharmacist, assistant pharmacist, medical practitioner, nurse, nurse practitioner, health officer, veterinary practitioner, pharmacy premises, prescription or other person, place or thing does not comply in every respect with the provisions of this Act; or[15]

(b) any provision of this Act has not been complied with,

an authorised officer may, in writing, direct any person who has contravened the provision by such non-compliance to take within a specified time, not exceeding 14 days, such steps as may be specified to prevent any further contravention and to remedy the matters in respect of which the non-compliance has occurred.

(2) The issue of a direction under this section does not affect any proceeding under this Act which has been or may be taken for the non-compliance which gave rise to the direction.

(3) A person to whom a direction is issued under this section and who does not comply with the direction commits an offence.

30 Contracts etc. void

(1) A contract, agreement, undertaking or understanding that is in effect when this Act comes into force is void to the extent to which it is inconsistent with this Act.

(2) Neither the Crown nor any person is liable to pay any damages or other compensation to any other person in consequence of subsection (1).

31 Making false or fraudulent representation

A person who, in an application for inclusion of a medicinal drug on the registered list or application for the issue of any licence under this Act, makes or produces or causes to be made or produced any false or fraudulent representation, certificate or affidavit, either verbally or in writing, and any person who knowingly aids or assists therein commits an offence and shall be liable on conviction to a fine not exceeding $2,000 or to imprisonment for a term not exceeding 12 months or both.

32 Offence and penalty

Any person who contravenes or fails to comply with any provision of this Act or any regulation made under this Act commits an offence, and on conviction shall, where no penalty is provided, be liable to a fine not exceeding $2,000, or imprisonment for a term not exceeding 12 months, or both; and in the case of a continuing offence, to a fine not exceeding $100 for every day or part of a day during which the offence has continued.

33 Offences by corporate bodies

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

34 Prosecutions

(1) Prosecutions for an offence under this Act may be brought —

(a) by or on behalf of the Attorney General;

(b) by a member of the police;

(c) by an authorised officer; or

(d) by a customs officer.

(2) A person referred to in subsection (1)(b), (c) or (d), whether or not a law practitioner, may lay institute or conduct any charge, information, complaint

or other proceedings arising under this Act, subject to any directions issued by the Attorney General.

35 Regulations

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

(a) the fees payable under this Act and the regulations;

(b) the manner and form of an application for inclusion of a new drug on the registered list or an application for any licence under this Act;

(c) exempting from the operation of any of the provisions of this Act or the regulations such persons or classes of persons as may be specified.

PART VIII - TRANSITIONAL ARRANGEMENTS

36 Temporary registered list

(1) The Committee shall create and maintain a temporary registered drug list to be based upon the List of Essential Drugs for the Kingdom kept by the Central Pharmacy and Medical Store.

(2) Medicinal drugs utilised, other than those on the List of Essential Drugs for the Kingdom, may be added to the temporary registered drug list provided that those medicinal drugs meet the criteria stated in section 7 of this Act.

(3) The temporary registered list shall cease to exist upon the creation of the registered list.

SCHEDULE

(Section 7(e))

COUNTRIES OF MANUFACTURE

Australia

Canada

Fiji

Sweden

United Kingdom

United States of America

New Zealand

ENDNOTES

[1] **Act 3 of 2001**

Amending Acts	Commencement
Act 7 of 2004	23 August 2004
Act 5 of 2012	30 July 2012
Act 1 of 2014	30 June 2014

[2] GS 12/2010

[3] Cap 28.28

[4] Cap 67, 1988 Revised Edition

[5] Cap 28.18

[6] Cap 28.24

[7] Inserted by Act 1 of 2014

[8] Cap 28.28

[9] Amended by Act 5 of 2012

[10] Amended by Act 5 of 2012

[11] Inserted by Act 1 of 2014

[12] Inserted by Act 1 of 2014

[13] Amended by Act 1 of 2014

[14] Amended by Act 1 of 2014

[15] Amended by Act 1 of 2014