



No. 10 of 1999.

Medicines and Cosmetics Act 1999.

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INDEPENDENT STATE OF PAPUA NEW GUINEA.

No. of 1999.

Medicines and Cosmetics Act 1999.

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INDEPENDENT STATE OF PAPUA NEW GUINEA.

No. of 1999.

AN ACT

entitled

Medicines and Cosmetics Act 1999,

Being an Act -

- (a) to make provisions with respect to medicinal products and medical advertisements and matters connected therewith; and
 - (b) to repeal the *Pharmacy Act* (Chapter 94) and the *Therapeutic Goods and Cosmetics Act 1984*; and
 - (c) to make consequential amendments to the *Poisons and Dangerous Substances Act* (Chapter 231),
- and for related purposes:

MADE by the National Parliament to come into operation in accordance with Section 5.

PART I. - PRELIMINARY.

1. COMPLIANCE WITH CONSTITUTIONAL REQUIREMENTS.

- (1) This Act, to the extent that it regulates or restricts the rights or freedoms conferred by Division III.3.C. (*Qualified rights*) of the *Constitution*, namely -
- (a) the right to freedom from arbitrary search and entry conferred by Section 44 of the *Constitution*; and
 - (b) the right to freedom of expression conferred by Section 46 of the *Constitution*; and
 - (c) the right to privacy conferred by Section 49 of the *Constitution*; and
 - (d) the right to freedom of movement conferred by Section 52 of the *Constitution*.
- is a law that is made for the purpose of giving effect to the public interest in public order and public welfare.

- (2) For the purposes of Section 41 of the *Organic Law on Provincial Governments and Local-level Governments*, it is declared that this Act relates to a matter of national interest.

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2. INTERPRETATION.

(1) In this Act, unless the contrary intention appears -

"advertisement", in relation to any product, means an advertisement published -

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

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

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

(d) in any other manner,

for the purposes of promoting, directly or indirectly, the sale or use of that product;

"analysis", in relation to any product, means any bacteriological, biochemical, biological, chemical, electrical, electrochemical, micro-biological, pathological, physical or other examination or test for ascertaining the presence or absence of any substance or organism or the composition or other qualities of that product;

"analyst" means a person appointed under Section 43;

"animal" includes any bird, fish or reptile;

"appointed day", in relation to a provision of this Act, means the date determined by the Minister under Section 5 to be the appointed day in relation to that provision;

"container", in relation to any product, means the vessel, bottle, tube, tin, box, case, wrapper, cover or other similar receptacle or envelope which immediately covers the product;

"cosmetic" means any substance or preparation, other than a medicament, intended to come into contact with the various external parts of the human body such as epidermis, hair system, nails, lips, eyelids, teeth, and mucous membranes, with a view to cleaning, protecting or keeping them in good condition, changing their appearance or perfuming or correcting their odour, but does not include a soap;

"dentist" means a person registered as a dentist under the *Medical Registration Act* (Chapter 398);

"Departmental Head" means the Departmental Head of the Department responsible for health matters;

"device" means any instrument, apparatus or contrivance, and includes any component, part or accessory of that instrument;

"expiry date", in relation to a product, means a day after which they may be expected to cease to conform to any standard applicable to it;

"inspector" means a person appointed under Section 34;

"label" includes any tag, brand, mark or written statement on, or attached to, or used in connection with, any container or package containing any product;

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- "licence" means a licence granted and issued under this Act and not cancelled or suspended;
- "licensing authority" means the Departmental Head;
- "manufacture", in relation to any product, means the manufacture or preparation of the product and includes -
- (a) any part of the manufacture or preparation of the product; and
 - (b) the packaging and labelling of the product;
- "medical practitioner" means a person registered as a medical practitioner under the *Medical Registration Act* (Chapter 398);
- "medical device" means any device -
- (a) the sole or principal use of which is, or ordinarily is, a therapeutic use; or
 - (b) that is represented to be, or might reasonably be taken to be, for medicinal purposes;
- "medicament" means a substance used internally or externally in medical treatment;
- "medicinal product" means a medicinal substance or a medical device intended for use for medicinal purposes;
- "medicinal purpose" means a use for the purpose of or in connection with -
- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in humans or animals; or
 - (b) influencing, inhibiting or modifying a physiological process in humans or animals; or
 - (c) testing the susceptibility of humans or animals to a disease or ailment; or
 - (d) destroying or inhibiting micro-organisms that may be harmful to humans or animals;
- "nurse" means a person registered as a nurse under the *Medical Registration Act* (Chapter 398);
- "package", in relation to any product, includes every means by which the product may, for transport or for storage or for sale, be cased, covered, enclosed, contained or packed;
- "Pharmacy Board" means the Pharmacy Board of Papua New Guinea established by Section 20;
- "pharmacist" means a person registered as a pharmacist with the Pharmacy Board or any person who had been registered as a pharmacist with the Papua New Guinea Medical Board under the *Medical Registration Act* (Chapter 398) prior to the commencement of this Act;
- "pharmacy licence" means a licence issued under Section 25;

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"pharmacy technician" means a person registered as a pharmacy technician with the Pharmacy Board or any person who had been registered as a pharmacy technician with the Papua New Guinea Medical Board under the *Medical Registration Act* (Chapter 398) prior to the commencement of this Act;

"premises" includes land, a ship, aeroplane or other vehicle or vessel;

"product" means a medicinal product, medical device or a cosmetic declared under Section 3 or 6 to be a medicinal product, medical device or a cosmetic to which this Act applies;

"product for animal use only" means, subject to Subsection (2), any product that -

(a) bears any particulars, in accordance with Subsection (2), that constitute, or might reasonably be taken for, a statement that the product is intended for animal use and not to be intended for human use; or

(b) is otherwise represented, whether by writing or otherwise, or otherwise purports, to be intended for animal use and not intended for human use;

"product licence" means a product licence granted under Part II;

"public institution" means -

(a) a Government Department or a public hospital or a university in the country; or

(b) any other institution or establishment which the Minister, by notice in the National Gazette, declares to be a public institution for the purposes of this Act;

"publish" includes cause, allow or permit to be published;

"Register of Pharmacists and Pharmacy Technicians" means the register established under Section 22(d);

"Register of Pharmacies" means the Register of Pharmacies established under Section 22(c);

"sale" includes sale whether by wholesale or retail, and 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 authorizing, directing, causing, permitting or attempting any of those acts or things;

"standards" means the standards referred to in Part III;

"substance" includes preparation or a mixture and all salts and derivatives of any substance;

"this Act" includes the regulations;

"veterinary surgeon" means a person registered as a veterinary surgeon under the *Veterinary Surgeons Act* (Chapter 98);

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"wholesale dealing", in relation to any product -

- (a) means the sale or supply of the product in the ordinary course of wholesale dealing for the purposes of resale; and
- (b) includes the sale or supply in wholesale quantities in the ordinary course of wholesale dealing and for use in any public institution or in connection with any prescribed profession, business, trade or industry carried on by any person who satisfies the wholesale dealer that he *bona fide* requires the product for use, but not for resale, in connection with that profession, business, trade or industry.

(2) For the purposes of the definition of "product for animal use only" in Subsection (1), a product is deemed to bear any particulars where those particulars are set out on -

- (a) the product or any part of the product; or
- (b) a container or package of the product or any part of the product; or
- (c) a label attached to the product or any part of the product; or
- (d) a label attached to a container or package of the product or any part of the product.

3. DECLARATION BY MINISTER IN CASE OF DOUBT.

The Minister may, by notice in the National Gazette, declare any product -

- (a) to be -
 - (i) a medicinal product; or
 - (ii) a medical device; or
 - (iii) a cosmetic; or
- (b) not to be -
 - (i) a medicinal product; or
 - (ii) a medical device; or
 - (iii) a cosmetic.

to which this Act applies where he is of the opinion that, but for the declaration, doubt would exist whether or not the product is a medicinal product, a medical device or a cosmetic, as the case may be, to which this Act applies.

4. EXEMPTIONS.

(1) The Minister may, by notice in the National Gazette, exempt a person or class of persons, or any product or class of products specified or described in the notice, from all of the provisions of this Act or such of the provisions of this Act as are specified or described in the notice.

(2) An exemption under this section may be made unconditionally or subject to such conditions as are specified or described in the notice.

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- (3) The licensing authority may permit the importation of any medicinal product -
- (a) by a person for the purpose of administering the medicinal product to himself or to any member of his family; or
 - (b) by a doctor, dentist or veterinary surgeon for the purpose of administering the medicinal product to a patient under his care; or
 - (c) by a pharmacist pursuant to any prescription given by a doctor, dentist or veterinary surgeon,

without a product licence where the quantity of the medicinal product does not exceed three months' supply based on the dosage recommended by the manufacturer or supplier of the product.

5. APPOINTED DAY.

(1) The Minister may, by notice in the National Gazette, fix a date to be an appointed day for the purposes of this Act.

(2) A date fixed by the Minister as an appointed day under Subsection (1) shall be the date on which -

- (a) a provision of this Act specified in the notice shall come into operation; and
- (b) the repeal of a provision of an Act repealed by Section 55 and specified in the notice shall come into effect; and
- (c) the repeal of a provision of the *Poisons and Dangerous Substances Act* (Chapter 231) and specified in the notice shall come into effect.

PART II. - CONTROL AND LICENSING OF PRODUCTS AND DEALERS OF PRODUCTS.

Division 1. - General.

6. DEALING, ETC., WITH PRODUCTS.

(1) The Minister may, by notice in the National Gazette, declare a medicinal product, a medical device or a cosmetic to be a product to which this Part applies.

(2) Subject to Subsection (3), a person, who, with effect from the appointed day, imports, manufactures, sells, supplies or otherwise deals with a product without a licence granted under this Part, is guilty of an offence.

Penalty: A fine of not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

(3) The Minister may, in relation to any medicinal product which was available for sale in Papua New Guinea immediately before the coming into operation of this Part, exempt by notice in the National Gazette such medicinal product from the application of Subsection (2) for such period as is specified in the notice.

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(4) The licensing authority may, on application in accordance with Division 2 by a person who is not the holder of a product licence, grant an import licence in accordance with Division 2 to that person to import, for sale or supply, a medicinal product that is not otherwise declared under Subsection (1) where the licensing authority is satisfied that the product is, in all respects, the same as a medicinal product registered under product licence.

7. MANUFACTURE OF PRODUCTS.

(1) Subject to Subsection (3), a person shall not, with effect from the appointed day, on any premises, manufacture for sale a product to which this Part applies unless the manufacture by him of that product is authorized by a licence granted under this Part.

(2) A person, who contravenes Subsection (1), is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

(3) The provisions of Subsection (2) do not apply to the manufacture of a medicinal product to which this Part applies -

- (a) by a medical practitioner or dentist for use in the treatment of a patient under his care; or
- (b) by a pharmacist on the premises on which the business of the pharmacist is carried out in open shop; or
- (c) on the premises of a public health institution for sale (otherwise than by wholesale) on or from those premises.

8. PRESCRIPTION ONLY, PHARMACY ONLY AND OVER THE COUNTER PRODUCTS.

(1) The licensing authority shall establish, maintain and publish -

- (a) a list of medicinal products that can only be dispensed or supplied by a pharmacist on a prescription given by a medical practitioner, dentist or veterinary surgeon; and
- (b) a list of medicinal products that can be sold or supplied without prescription issued by a medical practitioner, dentist or veterinary surgeon, but under the supervision of a pharmacist; and
- (c) a list of medicinal products that can generally be sold over the counter without the supervision of a pharmacist.

(2) A person, other than a medical practitioner, dentist, veterinary surgeon, pharmacist or a person licensed under this Act to do so, who sells or supplies a product specified in -

- (a) the list of prescription only medicinal products referred to in Subsection (1)(a); or

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(b) a pharmacy only medicinal product referred to in Subsection (1)(b), is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

(3) Notwithstanding Subsection (2), the supply of a medicinal product by a medical practitioner, dentist or veterinary surgeon shall be for treatment of his patients only.

Division 2. - Licences.

9. APPLICATION FOR LICENCE.

(1) A person may apply to the licensing authority for a product licence or a licence authorizing him -

- (a) to manufacture on specified premises a medicinal product or a cosmetic or a medicinal device; or
- (b) to sell by wholesale or retail a medicinal product or a cosmetic or a medicinal device; or
- (c) to import a medicinal product or a cosmetic or a medicinal device for sale or distribution; or
- (d) to sell by retail a medical device or a cosmetic or a medicinal device.

to which this Part applies.

(2) An application for a licence shall be -

- (a) in the prescribed form; and
- (b) lodged with the licensing authority; and
- (c) accompanied by the prescribed non-refundable application fee.

10. CONSIDERATION OF APPLICATION FOR LICENCE.

(1) In considering an application for a licence, the licensing authority shall take into consideration -

- (a) the safety, efficacy and quality of the product before granting a product licence; and
- (b) in relation to an imported product and in addition to Paragraph (a) the fact that the product is registered with the relevant licensing authority of the country from which it is to be imported and that it is manufactured in a factory approved for its manufacture by the licensing authority of that country; and
- (c) in relation to the premises in which manufacturing operation is to be carried out -
 - (i) the availability of manufacturing equipment; and
 - (ii) the qualifications of the person supervising the manufacturing operation; and
 - (iii) the storage and safekeeping of manufactured products; and
 - (iv) adequate record keeping; and

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- (d) the premises and the conditions for storage and safe keeping of the product, the availability of equipment and facilities for distribution and adequate record keeping before granting a wholesaler's licence or a licence for retailing.

(2) In considering an application under this section, the licensing authority may request the applicant to provide such further and better information as he considers necessary.

11. GRANT OF LICENCE.

(1) Where the licensing authority has considered an application under Section 10, he may -

- (a) grant the application and issue the licence; or
- (b) refuse the application and notify the applicant forthwith giving the reasons for the refusal.

(2) A product licence granted under Subsection (1)(a) -

- (a) shall be in the prescribed form; and
- (b) shall contain such conditions as are determined by the licensing authority and specified in the licence; and
- (c) is subject to the conditions specified in the licence; and
- (d) subject to Subsection (3), comes into force on the date specified in the licence, or, where a date is not specified, on the date on which it is granted; and
- (e) is subject to the payment of the prescribed licence fee; and
- (f) is not transferable.

(3) Notwithstanding Subsection (2)(d), a product licence shall not come into force unless the prescribed licence fee has been paid.

12. TERM OF LICENCE.

(1) A product licence shall be granted for a period not exceeding five years, and is renewable at the expiration of the term granted.

(2) A licence, other than a product licence, shall be granted for a period of one year and is renewable at the expiration of the term granted.

13. CANCELLATION OR SUSPENSION OF LICENCE.

(1) The licensing authority may, by written notice served on the holder of a licence, cancel or suspend the licence where the holder -

- (a) fails to pay the prescribed licence fee; or
- (b) is found guilty of an offence under this Act; or
- (c) fails to comply with the conditions of his licence; or

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- (d) makes a written request for his licence to be cancelled or suspended; or
- (e) ceases to operate or conduct the business for which the licence was issued under this Part.

(2) Where it is proposed to cancel or suspend a licence under Subsection (1), the licensing authority shall serve on the holder of the licence a notice -

- (a) advising the holder of the licence of the intention to cancel or suspend the licence and the reasons for the intended cancellation or suspension; and
- (b) requiring the holder of the licence within 14 days of the date of service of the notice to make representations to the licensing authority as to why the licence should not be cancelled or suspended.

(3) On the request of the holder of the licence within the period referred to in Subsection (2)(b), the licensing authority shall allow the holder of the licence an opportunity to be heard.

(4) Where the holder of the licence does not, within the period referred to in Subsection (2)(b), make representations under that subsection or submit a request to be heard under Subsection (3), the licensing authority may cancel or suspend the licence.

(5) The licensing authority shall consider any representations made under Subsection (2)(b) and, where appropriate, cancel or suspend the licence.

PART III. - STANDARDS.

14. STANDARDS TO WHICH PRODUCTS ARE TO CONFORM.

(1) All products which this Act applies are to conform to such standards as are prescribed.

(2) In prescribing the standards to which products are to conform, the regulations may adopt by reference the whole or part of any monograph contained in a prescribed edition of -

- (a) the *European Pharmacopoeia* published by or under the direction of the Council of Europe in pursuance of the Convention on the Elaboration of a European Pharmacopoeia; or
- (b) the *British Pharmacopoeia* published in the United Kingdom; or
- (c) the *International Pharmacopoeia* published under the direction of the World Health Organisation; or
- (d) such other publications as are prescribed.

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15. SALE OF PRODUCTS NOT IN CONFORMITY WITH STANDARDS.

(1) A person, who sells a product that does not conform to the standard prescribed in relation to that product, is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

(2) It is a defence to an offence under Subsection (1) where the seller proves that at the time of the sale, he had no reason to suppose, and did not in fact suppose, that the product did not conform to the standard prescribed and -

- (a) where the regulations make provision for or with respect to the determination of the person whose duty it is to ensure conformity with the standard in relation to the product - that it was not his duty to ensure conformity with the standard; or
- (b) where the regulations do not so provide - that it was not reasonable to expect that he should have been able to ensure conformity with the standard in so far as the ensuring of conformity with that standard related to acts, matters or things outside his control.

(3) Where, in accordance with a standard in relation to any product, any prescribed information or statement appears on the label, container or package of the product, the product shall be deemed not to conform to that standard where there is included thereon any comment, reference or explanation that expressly or impliedly contradicts, qualifies or modifies that information or statement.

PART IV. - ADVERTISEMENTS, ETC.,

16. INTERPRETATION.

For the purposes of this Part. "representation", in relation to any medicinal product, means a representation, whether expressed or implied, with respect to the use or consumption of that product for the purpose of, or in connection with, a medicinal purpose.

17. PROHIBITION OF CERTAIN REPRESENTATIONS IN ADVERTISEMENTS.

(1) A person shall not publish an advertisement in respect of -

- (a) any medicinal product where it contains a representation prescribed as a prohibited representation; or
- (b) any prescribed medicinal product where it contains a representation prescribed as a prohibited representation; or
- (c) any prescribed medicinal product where it contains a representation prescribed as a required representation; or
- (d) any prescribed medicinal product where it contains a representation other than a representation prescribed as a required representation under Paragraph (c).

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(2) A person shall not publish an advertisement in respect of any prescribed medicinal product.

(3) A person, who publishes an advertisement that contains any representation where the advertisement contains any comment, reference or explanation that expressly or impliedly contradicts, qualifies or modifies any representation prescribed for the purposes of Subsection (1), is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

(4) Nothing in Subsection (1) or (2) applies in respect of any representation contained in an advertisement that is contained in any journal the circulation of which is intended to be limited to persons who are medical practitioners, pharmacists, dentists, veterinary surgeons or nurses or who are engaged in the business of selling by wholesale medicinal products or that is contained in any other document that is intended to be published exclusively to or among such persons.

(5) Nothing in this section affects the operation of any other provision of this Act that relates to standards with respect to the labelling of medicinal products.

18. ADVERTISEMENTS TO CONTAIN NAME, ETC.,

(1) Except as provided by the regulations, a person who publishes an advertisement for any medicinal product shall include in that advertisement the name and address of the person authorizing the publication of the advertisement and such other information as may be prescribed.

(2) Nothing in this section -

(a) applies in respect of any advertisement that is published orally or by any means of producing or transmitting light or sound; or

(b) affects the operation of any other provisions of this Act that relate to standards with respect to the labelling of medicinal products.

19. ORDER PROHIBITING FALSE OR MISLEADING REPRESENTATION OR NAMES.

(1) Where the Minister is of the opinion that a representation, where made in respect of a medicinal product, or a claim, where made in respect of a cosmetic, would be false or misleading, he may, by written notice served on a person specified or described in the notice, prohibit that person from publishing an advertisement that contains that representation or claim (whether expressed or implied) made in respect of the product or cosmetic.

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(2) Where the Minister is of the opinion that the name of any medicinal product or cosmetic, where sold or advertised under that name, would be misleading, he may, by written notice served on a person specified or described in the notice, prohibit that person from selling that product or cosmetic under that name or from publishing any advertisement advertising the product or cosmetic under that name.

(3) A prohibition under this section takes effect from a date specified in the notice, being a date not earlier than seven days after the service of the notice.

(4) A person, who -
(a) publishes an advertisement; or
(b) sells a medicinal product or cosmetic,
in contravention of Subsections (1), (2) or (3), is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

(5) A notice may be given under this section in relation to a representation whether or not that representation may be made under Section 17.

(6) A person found guilty of an offence under Section 17 or under this section in respect of a representation contained in an advertisement is not liable for conviction for an offence under the other of those sections in respect of the same representation contained in that advertisement.

PART V. - PHARMACIES.

Division 1. - Establishment of the Pharmacy Board.

20. ESTABLISHMENT OF PHARMACY BOARD.

(1) There is established the Pharmacy Board of Papua New Guinea.

(2) The Pharmacy Board shall consist of -

- (a) the Departmental Head, *ex officio*, who shall be the Chairman of the Board; and
- (b) the Head of the Pharmaceutical Services Section of the Department responsible for health matters, *ex officio*, who shall be the Deputy Chairman of the Board; and
- (c) the officer responsible for the function of the Pharmaceuticals of the Pharmaceutical Services Section of the Department responsible for health matters, *ex officio*, who shall be the Secretary of the Board; and

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- (d) one person representing the University of Papua New Guinea School of Pharmacy nominated by that University; and
 - (e) one person representing the private pharmaceutical sector nominated by the Minister.
- (3) The members referred to in Subsection (2)(d) and (e) -
- (a) shall be appointed by the Minister by notice in the National Gazette; and
 - (b) shall hold office for a period not exceeding three years; and
 - (c) are eligible for re-appointment; and
 - (d) shall hold office on such terms and conditions of appointment as are determined under the *Boards (Fees and Allowances) Act* (Chapter 299).

21. DETERMINATION OF PHARMACY BOARD PROCEDURAL REQUIREMENTS, ETC.,

- (1) The manner of -
- (a) leave of absence of members; and
 - (b) vacation of office of members, other than *ex officio* members; and
 - (c) calling of meetings; and
 - (d) meetings of the Pharmacy Board; and
 - (e) the establishment of committees of the Pharmacy Board,
- are as determined by the Pharmacy Board.

(2) The exercise of a power or the performance of a function of the Pharmacy Board is not invalidated by reason only of a vacancy in the membership of that Board.

(3) A member of the Pharmacy Board or of a committee or an officer of that Board is not personally liable for any act or default of himself or that Board, done or omitted to be done in good faith in the operations of that Board, or for the purposes of that Board.

22. FUNCTIONS OF THE PHARMACY BOARD.

The functions of the Pharmacy Board are -

- (a) to determine the standards of knowledge and skill to be attained by a person seeking to become a pharmacist or pharmacy technician and to review those standards from time to time; and
- (b) to provide for formal registration of pharmacists and pharmacy technicians; and
- (c) to establish and maintain a register to be known as the Register of Pharmacies and to enter in that register the names of pharmacies registered under this Act; and
- (d) to establish and maintain a register to be known as the Register of Pharmacists and Pharmacy Technicians and enter in that register the names of pharmacists and pharmacy technicians registered under this Act; and

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- (e) to publish from time to time a list of all those persons whose names are entered in the Register of Pharmacists and Pharmacy Technicians; and
- (f) to recommend to the Minister addition and deletion of items in the medicinal products list; and
- (g) to carry out the evaluation of drugs submitted for registration; and
- (h) to recommend to the licensing authority for the final approval of products for registration; and
- (i) to recommend to the licensing authority, for exemption from registration, products for special circumstances requiring specialist treatment; and
- (j) to perform any other duties as the licensing authority may determine from time to time.

Division 2. - Registration and licensing of Pharmacies.

23. REGISTRATION OF PHARMACIES.

- (1) A person who operates a pharmacy -
 - (a) shall register and licence the pharmacy under this Act; and
 - (b) ensure that the operations of the pharmacy are carried out under the full supervision of a registered pharmacist.

- (2) A person, who contravenes Subsection (1), is guilty of an offence.
Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

24. APPLICATION FOR REGISTRATION OF A PHARMACY.

- (1) An application for registration of a pharmacy shall be -
 - (a) in the prescribed form; and
 - (b) accompanied by the prescribed application fee; and
 - (c) lodged with the licensing authority.

- (2) In considering an application for registration of a pharmacy, the licensing authority shall take into consideration -
 - (a) the amount of space available for compounding, dispensing and storage of medicinal products; and
 - (b) the storage conditions for medicinal products; and
 - (c) the recording of prescriptions dispensed and medicinal products to be sold by wholesale; and
 - (d) the equipment and facilities for compounding and dispensing medicinal products.

- (3) In considering an application under this section, the licensing authority may request the applicant to provide such further and better information as he considers necessary.

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25. GRANT OF PHARMACY REGISTRATION AND LICENCE.

(1) Where the licensing authority has considered an application under Section 24, he may -

- (a) grant the application and -
 - (i) register the pharmacy in the Register of Pharmacies; and
 - (ii) issue a pharmacy licence to the applicant; or
- (b) refuse the application and notify the applicant forthwith giving the reasons for the refusal.

(2) A pharmacy licence granted under Subsection (1) -

- (a) shall be in the prescribed form; and
- (b) shall contain such conditions as determined by the licensing authority and specified in the licence; and
- (c) is subject to the conditions specified in the licence; and
- (d) subject to Subsection (3), comes into force on the date specified in the licence or, where no date is specified, on the date on which it was granted; and
- (e) is subject to the payment of the prescribed licence fee; and
- (f) is not transferable.

(3) Notwithstanding Subsection (2)(d), a pharmacy licence shall not come into force unless the prescribed licence fee has been paid.

26. TERM OF PHARMACY LICENCE.

A pharmacy licence shall be granted for a period not exceeding one year, and is renewable at the expiration of the term granted.

27. CANCELLATION OR SUSPENSION OF PHARMACY LICENCE.

(1) A licensing authority may, by written notice on the holder of a pharmacy licence, cancel or suspend the pharmacy licence where the licence holder -

- (a) fails to pay the licence fee; or
- (b) is found guilty of an offence under this Act; or
- (c) fails to comply with the conditions of his pharmacy licence; or
- (d) makes a written request for his pharmacy licence to be cancelled or suspended;
or
- (e) ceases to operate or conduct the business for which the pharmacy licence was issued.

(2) Where it is proposed to cancel or suspend a pharmacy licence under Subsection (1), the licensing authority shall serve on the holder of the pharmacy licence a notice -

- (a) advising the holder of the pharmacy licence of the intention to cancel or suspend the pharmacy licence and the reasons for the intended cancellation or suspension; and

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(b) requiring the holder of the pharmacy licence within 14 days of the date of service of the notice to make representations to the licensing authority as to why the pharmacy licence should not be cancelled or suspended.

(3) On the request of the holder of the pharmacy licence within the period referred to in Subsection (2)(b), the licensing authority shall allow the holder of the pharmacy licence an opportunity to be heard.

(4) Where the holder of the pharmacy licence does not, within the period referred to in Subsection (2)(b), make representations under that subsection or submit a request to be heard under Subsection (3), the licensing authority may cancel or suspend the pharmacy licence.

(5) The licensing authority shall consider any representations made under Subsection (2)(b) and, where appropriate, cancel or suspend the pharmacy licence.

(6) Where a pharmacy licence has been cancelled under this section, the registration of the pharmacy in respect of which the pharmacy licence was issued shall be deemed cancelled.

28. REGULATION OF PHARMACISTS.

(1) Subject to Subsections (2), (3) and (4), a person, other than a registered pharmacist, who -

- (a) carries on or attempts to carry on, in any place and on any occasion, the business of a pharmacist; or
- (b) pretends to be a pharmacist; or
- (c) assumes and uses the title of pharmaceutical chemist, pharmacist, pharmacist, chemist, homeopathic chemist, dispensing chemist or dispensing druggist or any other title of a similar meaning; or
- (d) uses or exhibits any title, term, sign or symbol that may reasonably be construed to mean that he -
 - (i) is qualified to perform the functions of a pharmacist; or
 - (ii) is carrying on the business of a pharmacist,

is guilty of an offence.

Penalty: A fine not exceeding K5,000.00.

(2) Subsection (1) does not apply to the ownership of a pharmacy business.

(3) On the death of a pharmacist who was actually in business as a pharmacist at the time of his death, his executor, administrator or trustee may continue the business for a period of 12 months, or such a longer period as the licensing authority allows, where the business is *bona fide* carried on under the personal supervision of a registered pharmacist.

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(4) A medical practitioner, dentist or veterinary surgeon may dispense, compound or make up medicinal products for patients or animals under his professional care, without being registered as a pharmacist.

(5) A retail storekeeper or shopkeeper, who sells medicinal products included in the list published under Section 8(1)(c), shall not be deemed, for the purposes of this act, to be carrying on the business of a pharmaceutical chemist.

29. DUTIES OF PHARMACISTS.

(1) A pharmacist who -

- (a) keeps or maintains a shop for selling or supplying medicines or drugs or for dispensing, compounding or making up prescriptions without the shop being constantly under his personal control and supervision or that of some other pharmacist while open for business; or
- (b) permits a person other than -
 - (i) a pharmacist; or
 - (ii) a *bona fide* assistant in the course of his employment and under his actual personal supervision, to sell or supply medicinal products, or dispense, compound or make-up prescriptions; or
- (c) carries on the business of a pharmacist otherwise than under the actual supervision of himself or some other pharmacist; or
- (d) adopts the title 'consulting chemist'; or
- (e) gives medical or surgical advice or aid -
 - (i) in the case of simple ailments of common occurrence; or
 - (ii) in the administration of antidotes in cases of actual poisoning; or
 - (iii) in the application of immediate aid in cases of accident or injury; or
 - (iv) in urgent cases under the direct instruction of a medical practitioner, other than in his place of business; or
- (f) allows his name to be used in connection with the carrying on of the business of a pharmacist in any premises at which there is no pharmacist in daily attendance; or
- (g) aids or assists any person other than a pharmacist to carry on the business of a pharmacist except in accordance with the provisions of this Act.

is guilty of an offence.

Penalty: A fine not exceeding K5,000.00.

(2) A pharmacist who conducts a pharmacy business shall have his name legibly painted or written and continually maintained in that form, in a conspicuous place in the pharmacy where the business is carried on.

(3) A pharmacist shall record, in the prescribed manner, in a book to be kept by him for that purpose, every prescription of a medical practitioner dispensed, compounded or made up by him.

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- (4) A person who contravenes Subsection (2) or (3) is guilty of an offence.
Penalty: A fine not exceeding K3,000.00.

30. SUPPLY OF CERTAIN MEDICINAL PRODUCTS, ETC.,

(1) Subject to Subsection (2), a person, other than a medical practitioner or a person acting under the direct instructions of a medical practitioner, who -

- (a) attends on; or
- (b) prescribes for; or
- (c) supplies any article, except condoms, as a medicinal product, instrument or appliance to

any person for -

- (d) the alleviation, cure or treatment of -
 - (i) a venereal disease (whether or not the person is suffering from a venereal disease); or
 - (ii) a disease affecting the generative organs or functions; or
 - (iii) sexual impotence; or
 - (iv) any complaint or infirmity arising from or relating to sexual intercourse; or
 - (v) female menstrual irregularities; or
- (e) for the purpose of terminating or influencing the course of pregnancy,

is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

(2) Subsection (1) does not apply to a pharmacist who -

- (a) dispenses to the patient of a medical practitioner that medical practitioner's prescription where it is dated and bears the address and usual signature of the practitioner; or
- (b) sells or supplies in the ordinary course of his business a medicinal product, medical device or cosmetics for purposes other than a purpose referred to in Subsection (1).

31. CERTAIN PROHIBITED ADVERTISEMENTS.

(1) For the purposes of this section, "statement" includes a book, document or paper containing a statement.

(2) Subject to Subsection (3), a person who, on his own behalf or as an assistant, servant, agent or manager of another, publishes or permits the publication of any statement, whether by way of advertisement or otherwise, to promote the sale of any article as a medicinal product, instrument or appliance -

- (a) for the alleviation, cure or treatment of -
 - (i) a venereal disease; or

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- (ii) a disease affecting the generative organs or functions; or
- (iii) sexual impotence; or
- (iv) any complaint or infirmity arising from or relating to sexual intercourse; or
- (v) female menstrual irregularities; or
- (b) for the purpose of -
 - (i) terminating or influencing the course of pregnancy; or
 - (ii) preventing conception,

is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

- (3) Subsection (1) does not apply in respect of -
 - (a) a book, document or paper published in good faith for the advancement of medical or surgical science; or
 - (b) an advertisement, notice or recommendation published by the authority of the Departmental Head; or
 - (c) a publication sent only to medical practitioners, dentists; veterinary surgeons, pharmacists or nurses.

32. INSTITUTION OF PROSECUTIONS.

A prosecution for an offence under this Part may be instituted by the licensing authority or by any other person authorized by him for the purpose.

PART VI. - INSPECTION AND SEIZURE OF PRODUCTS.

33. APPLICATION OF THIS PART.

This Part applies to -

- (a) a product that is a medicinal product or cosmetic and is for sale or is intended for sale (whether or not the product is to be the subject of further manufacture) other than a product prescribed to be a product to which this section does not apply; or
- (b) a product, which an inspector believes on reasonable grounds, to be a product referred to in Paragraph (a).

34. APPOINTMENT OF INSPECTORS.

(1) The licensing authority may, by notice in the National Gazette, appoint an officer of the Public Service or such other suitably qualified person to be an inspector for the purposes of this Act.

(2) The licensing authority shall provide an inspector with a certificate of appointment.

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35. POWERS OF INSPECTORS.

(1) For the purpose of ascertaining whether the provisions of this Act are being complied with, an inspector, on production of his certificate of appointment, may, in respect of a product to which this Part applies -

- (a) enter, inspect or search, at any reasonable time, any premises which he believes on reasonable grounds are used for or with respect to the manufacture, distribution, conveyance, storage, handling or sale of the product; or
- (b) require the production of and inspect and make copies of or take extracts from, any book or document relating to the manufacture of or any dealing in the product; or
- (c) require the production of the product; or
- (d) open and examine any receptacle, container or package which he believes on reasonable grounds may contain the product; or
- (e) examine the product; or
- (f) seize and remove for analysis portions or samples of the product; or
- (g) subject to Subsection (2), seize, the product.

(2) Without affecting his powers under Subsection (2)(f) and notwithstanding anything contained in this section, an inspector shall not seize any product under Subsection (2)(g) -

- (a) unless the inspector believes on reasonable grounds that there has been a contravention of any of the provisions of this Act with respect to the product; and
- (b) in the case of a product that is in the possession, care, custody or control of any manufacturer of the product - unless the inspector believes on reasonable grounds that the product is for sale or is, without further manufacture other than packaging or labelling, intended for sale.

36. RELEASE OF SEIZED PRODUCTS.

(1) A product seized under Section 35 shall be released on the expiration of the prescribed period after the seizure unless -

- (a) forfeiture of the goods is consented to under Section 40; or
- (b) a District Court orders under Section 37 that the product be forfeited.

(2) A product seized under Section 35 may be released before the expiration of the prescribed period.

(3) The release of any product under Subsection (1) or (2) shall be made -

- (a) by or at the direction of the inspector who seized them or of the Departmental Head; and
- (b) to the owner of the goods or the person who had the possession, care, custody or control of the product at the time of the seizure.

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(4) Nothing in this section requires the release of any product or any part of the product damaged or destroyed in the course of an analysis of the product in accordance with this Act.

(5) A District Court may, on application, extend the period referred to in Subsection (1).

37. ORDERS THAT SEIZED PRODUCTS BE FORFEITED.

(1) A District Court may order that on the expiration of any period specified in the order, a product seized under Section 35 be forfeited to the State.

(2) An order under this section shall not have effect in respect of a product released under Section 36.

38. EXPENSES OF SEIZURE, ETC.,

(1) A District Court may order the owner or the person in whose possession a product was seized under Section 35 to pay to the State the reasonable expenses of seizing, forfeiting and disposing of the product and, where the product is submitted for analysis under Section 44, the reasonable expenses of the analysis.

(2) An order may be made under Subsection (1) in respect of -

- (a) a product the forfeiture of which is or was consented to under Section 40; or
- (b) a product specified in an order under Section 37.

39. STORAGE, ETC., OF SEIZED PRODUCTS.

(1) Subject to any direction of the Departmental Head, a product seized under this Part may, at the option of the inspector who seized the product, be -

- (a) kept or stored on the premises on which it was seized; or
- (b) taken to such other place as the inspector thinks fit to be kept or stored until released or disposed of under this Act.

(2) A person shall not remove, alter or interfere in any way with a product seized under this Part without the authority of the inspector who seized the product or the Departmental Head.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

40. FORFEITURE OF PRODUCTS BY CONSENT.

Where an inspector has seized a product under Section 35 and the owner of the product or the person in whose possession, care, custody or control the goods was or at the time of the seizure consents in writing to their forfeiture, the product shall accordingly be forfeited to the State.

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41. DISPOSAL OF FORFEITED PRODUCTS.

Any product forfeited to the State under this Part may be disposed of in such manner as the Departmental Head may, generally or in any particular case or class or cases, direct.

42. OBSTRUCTION OF INSPECTORS.

A person, who -

- (a) wilfully delays or obstructs an inspector in the exercise of any of his powers under this Act; or
- (b) fails to produce any product, book or document which he is required to produce under this Act, unless the product, book or document is not in his possession, care, custody or control,

is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

PART VII. - MISCELLANEOUS.

43. APPOINTMENT OF ANALYSTS, ETC.,

(1) The licensing authority may, by notice in the National Gazette, appoint a person to be an analyst for the purposes of this Act.

(2) As soon as practicable after the prescribed date in each year, the licensing authority shall cause to be published in the National Gazette a list of all persons who have been appointed as analysts under Subsection (1) as at the date of publication.

44. ANALYSIS.

(1) An inspector may submit any product seized under Section 35(1)(f) or (g) to an analyst for analysis.

(2) Where an analysis has been made by an analyst or under the personal supervision of an analyst in respect of any product submitted under Subsection (1), the analyst shall issue a certificate setting out the results of that analysis.

(3) Where a certificate has been issued under Subsection (2) setting out the results of an analysis made in respect of any product, the owner of the product or the person in possession, care, custody or control of the product at the time of its seizure shall, on payment of the prescribed fee, be supplied with a copy of the certificate.

(4) A person, who uses any analysis made for the purposes of this section for the purposes of trade or advertisement, is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

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45. MINISTER MAY REQUIRE INFORMATION AS TO MEDICINAL PRODUCTS, ETC.,

(1) The Minister may, by written notice served on a person who manufactures, imports or sells a medicinal product or cosmetic specified in the notice, require that person to furnish in writing to the Minister or such other person as may be specified in the notice, within such time, not being less than 14 days as specified in the notice, such information relating to the medicinal product or cosmetic as the Minister requires.

(2) A notice referred to in Subsection (1) may be served on any person whether or not the medicinal product or cosmetic referred to in the notice is a medicinal product or cosmetic in respect of which information has previously been furnished.

(3) A person on whom a notice is served under Subsection (1) shall comply with the notice within the time specified in the notice.

(4) A person on whom a notice is issued under Subsection (1) shall not knowingly furnish any information that is false or misleading in a material particular.

(5) A person, who -

(a) fails to comply with Subsection (1), (2) or (3); or

(b) contravenes Subsection (4),

is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding six months, or both.

46. MINISTERIAL ORDERS IN RELATION TO MEDICINAL PRODUCTS AND COSMETICS.

(1) The Minister may, where it appears to him to be necessary to do so in the interest of public safety, by order, prohibit the sale, supply or importation of a medicinal product or cosmetic specified in the order.

(2) A prohibition imposed by the order under Subsection (1), may be a total prohibition or may be imposed subject to such exemptions as may be specified in the order.

47. PROHIBITION OF SALE BY AUTOMATIC MACHINES.

(1) For the purposes of this section, "automatic machine" means a machine or mechanical device used or capable of being used for the purpose of selling or supplying a medical product (excluding condoms) without the personal manipulation or attention of the seller or supplier or his employee or other agent at the time of the sale or supply.

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- (2) A person, who -
- (a) whether on or about his premises or elsewhere:-
 - (i) installs an automatic machine for the sale or supply of any medicinal product; or
 - (ii) sells or supplies any medicinal product by means of an automatic machine; or
 - (b) allows or permits an automatic machine to be installed on his premises; or
 - (c) places or allows or permits to be placed, any medicinal product in an automatic machine on his premises or under his control; or
 - (d) allows or permits a person to purchase or be supplied with or otherwise obtain a medicinal product by means of an automatic machine on the premises or under the control of that person,

is guilty of an offence.

Penalty: A fine not exceeding K5,000.00 or imprisonment for a term not exceeding 12 months, or both.

Default Penalty: K100.00 for each day the offence is continued after the conviction.

48. HAWKING, ETC., OF MEDICINAL PRODUCTS.

- (1) A person, who -
- (a) sells in any street or from house to house; or
 - (b) hawks or peddles; or
 - (d) subject to Subsection (2), distributes free or as samples in a street or a public place or from house to house,

a medicinal product, is guilty of an offence.

Penalty: A fine not exceeding K2,500.00.

(2) Subsection (1) does not apply to the free distribution of clinical samples of a medicinal product to medical practitioners, pharmacists, dentists or manufactures of, or wholesalers of, a medicinal product where the distribution is made to the medical practitioner, pharmacist, dentist or veterinary surgeon personally or by posting a letter or parcel containing the product addressed to him.

49. EVIDENCE.

(1) In any legal proceedings under this Act, a certificate purporting to be signed by the Departmental Head or by a person authorized generally or specially by the Departmental Head to do so, certifying that a person named in the certificate -

- (a) was or was not the holder of a licence or other authority under this Act; or
- (b) was, as the case requires, an analyst or an inspector, on a particular day, or during a particular period specified in the certificate,

is admissible in evidence and is sufficient evidence of the fact so certified.

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(2) In any legal proceedings under this Act, a certificate purporting to be signed by an inspector certifying that a matter specified in the certificate is a copy of, or extract from, a book or document, made or taken by him under this Act, shall be admissible in evidence without production of the book or document.

(3) In any legal proceedings under this Act, a certificate purporting to be signed by an analyst and setting out the results of an analysis of a product under Section 44 shall be sufficient evidence of the identity of the product analysed, of the result of the analysis and that the analysis was carried out in such manner as is specified in the certificate.

50. LIABILITY OF EMPLOYERS FOR ACTS OF EMPLOYEES.

(1) Where any person as the employee of another person contravenes this Act or is guilty of an offence against this Act, the employer is also guilty of the offence, whether or not the offence was committed without his authority or contrary to his orders or instructions, unless he proves that he had no knowledge of the commission of the offence and could not, by the exercise of due diligence, have prevented the commission of the offence.

(2) The employer may be convicted of an offence in accordance with Subsection (1) notwithstanding that the employee has not been charged or convicted of the offence.

(3) Nothing in Subsection (1) prejudices or affects any liability imposed by or under this Act on any person by whom an offence against this Act is actually committed.

51. OFFENCES BY CORPORATIONS.

Where a corporation does an act or makes any omission that is an offence under this Act, every person who at the time of the act or omission was a director or member of the governing body of the corporation or is concerned in the management of the corporation, and who authorized or knowingly permitted the act or omission, shall, for the purposes of this Act, be deemed to have committed the offence.

52. APPEALS AGAINST DECISIONS OF LICENSING AUTHORITY.

(1) A person whose application for a licence or a renewal of licence has been refused by the licensing authority under this Act may appeal to the Minister.

(2) An appeal under this section shall be -

- (a) made in writing; and
- (b) lodged with the Minister within 30 days of the date of refusal of the application; and
- (c) accompanied by the prescribed fee.

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(3) In the exercise of his power to determine an appeal under this section, the Minister may -

- (a) dismiss the appeal; or
- (b) require the licensing authority to grant the licence or renewal of licence, and the licensing authority shall give effect to the Minister's decision.

(4) The Minister's decision under this section is final.

53. ADVISORY COMMITTEES.

The Minister may establish one or more advisory committees consisting of such members as he may appoint for the purpose of giving advice to the licensing authority with regard to such matters arising out of or in relation to the administration of this Act.

54. REGULATIONS.

The Head of State, acting on advice, may make regulations, not inconsistent with this Act, prescribing all matters which by this Act are required or permitted to be prescribed or that are necessary or convenient to be prescribed for carrying out or giving effect to this Act, and in particular for prescribing -

- (a) the conditions to be complied with as to the situation and construction of premises used for the manufacture or storage of medicinal products or cosmetics, securing the sanitation of those premises and the provision of facilities for protecting those medicinal products or cosmetics from contamination or deterioration; and
- (b) the conditions to be complied with in the manufacture, importation, distribution, conveyance, storage or handling of medicinal products or cosmetics to determine conformity with the prescribed standards; and
- (c) the methods of analysis of medicinal products or cosmetics to determine conformity with the prescribed standards; and
- (e) the manner of delivering up of licences issued under this Act, and the issue of substitute or duplicate licences; and
- (e) the types of records to be kept by persons engaged in the manufacture, importation, distribution, conveyance, storage, handling or sale of medicinal products; and
- (f) the procedure to be adopted by inspectors on the seizure and removal for analysis portions or samples of products; and
- (g) the conditions to be complied with in respect of the free distribution of clinical samples of medicinal products; and
- (h) medical devices or classes of medical devices the sale of which is prohibited or the conditions under which medical devices may be sold; and
- (i) the standards to which products shall conform, being standards that relate to -
 - (a) the composition, strength, potency, stability, purity, quality construction or other properties; and

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- (b) the manufacture and quantity of medicinal products; and
- (c) the packaging and labelling of medicinal products; and
- (d) the storage, handling or conveyance of medicinal products; and
- (j) the substances that shall not be contained in any product; and
- (k) the substances and the quantities or proportions of those substances that may be contained in any product; and
- (l) information or statements that are to appear or not to appear on labels, containers or packages of products; and
- (m) the manner of determining expiry dates of medicinal products; and
- (n) the requirements to which products are to conform when sold; and
- (o) the manner of determining the persons whose duty it is to ensure conformity with a standard before or at the time of sale of the products to which the standard relates; and
- (p) the circumstances under which products sold after the expiry date may or may not be deemed to conform to a prescribed standard relating to those products; and
- (q) modifications to monographs or parts of monographs; and
- (r) the manner of -
 - (i) the conduct of clinical trials; and
 - (ii) the issue of clinical trial certificates; and
 - (iii) the exemption of clinical trials from any provisions of this Act: and
- (s) the manner of the publication of advertisements of medicinal products; and
- (t) the imposition of requirements necessary or expedient for -
 - (i) the labelling of containers or packages of medicinal products; and
 - (ii) the display of distinctive marks on containers and packages of medicinal products; and
 - (iii) leaflets relating to medicinal products; and
- (u) the control of professional conduct of pharmacists and the practice of the profession; and
- (v) the conditions under which medicinal products may be manufactured, dispensed, compounded or sold; and
- (w) the extent to which the *British Pharmaceutical Codex* published in the United Kingdom by the direction of the Pharmaceutical Council of Great Britain, or the *Australian Pharmaceutical Forum Law* published by the Australian Pharmaceutical Conference on behalf of the Pharmaceutical Societies of Australia and New Zealand shall be accepted as a statement of official standards of quality or composition of medicinal products and of the compounding of all mixtures of medicinal products; and
- (x) the imposition of fines not exceeding K5,000.00 for breaches of the regulations; and
- (y) the fixing of fees required by this Act to be prescribed or necessary or convenient to be levied in relation to matters prescribed in the regulations.

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PART VIII. - REPEAL, SAVINGS AND TRANSITIONAL.

55. REPEAL.

Subject to Section 5(2) -

- (a) the following Acts are repealed:-
 - (i) the *Pharmacy Act* (Chapter 94); and
 - (ii) the *Therapeutic Goods and Cosmetics Act 1984*; and
- (b) the provisions of the *Poisons and Dangerous Substances Act* (Chapter 231) and as are specified in a notice made under Section 5(2)(c) are repealed.

56. SAVING OF EXISTING LICENCES, ETC.,

(1) Subject to Subsection (2), all licences, permits or other authorities granted under an Act repealed by Section 55 and valid and in force immediately before the coming into operation of this Act, shall, on that coming into operation, continue to have full force and effect for the term for which they were granted or made or until they sooner expire or are revoked according to law as if the Act under which they were granted or made had not been repealed.

(2) Where the licensing authority is of the opinion that any term or condition of any licence, permit or other authority granted under an Act repealed by Section 55 is at variance with the provisions of this Act to an extent which makes it unacceptable, he shall by written notice -

- (a) advise the holder of the licence, permit or other authority of the term or condition that is unacceptable; and
- (b) specify the variation in the term or condition required to ensure compliance with this Act; and
- (c) intimate that the variation shall apply in respect of the licence, permit or other authority, as the case may be, with effect from a date specified in the notice, unless he receives notification from the holder of the licence, permit or other authority, as the case may be, that such variation is unacceptable, in which case the licence, permit or other authority, as the case may be, shall cease to have effect and shall be deemed cancelled from the date specified.

57. ACTIONS, ETC., NOT TO ABATE.

Where, immediately before the coming into operation of this Act, any action, arbitration or proceeding was pending or existing by or against a person or body under an Act repealed by Section 55, it does not, on that coming into operation, abate or discontinue, or be in any way affected by any provision of this Act but it may be prosecuted, continued and enforced by, against or in favour of the person or body as if this Act had not been made.

Medicines and Cosmetics

58. APPLICATION OF ACTS, ETC.,

Where –

(a) any enactment or subordinate enactment other than this Act; or

(b) any document or instrument wherever made or executed,

contains a reference, express or implied, to a statutory provision repealed by Section 55, that reference shall, after the date of repeal of the provision, be read and construed and have effect as a reference to the corresponding provision of this Act.

I hereby certify that the above is a fair print of the *Medicines and Cosmetics Act 1999* which has been made by the National Parliament.

Clerk of the National Parliament.

I hereby certify that the *Medicines and Cosmetics Act 1999* was made by the National Parliament on 29 September 1999 by an absolute majority in accordance with the Constitution.

Speaker of the National Parliament.