Health Products Bill

Bill No. /2005.

Read the first time on 2005.

THE HEALTH PRODUCTS ACT 2005

(No. of 2005)

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A BILL

i n t i t u l e d

An Act to regulate the manufacture, import, supply, presentation and advertisement of health products and active ingredients used in the manufacture thereof, and to provide for matters connected therewith; to provide for the transition of the regulation of medicinal products from the Medicines Act (Chapter 176 of the 1985 Revised Edition) to this Act and thereafter to repeal the Medicines Act; to amend and rename the Medicines (Advertisement and Sale) Act (Chapter 177 of the 1985 Revised Edition), to repeal the Poisons Act (Chapter 234 of the 1999 Revised Edition) and the Sale of Drugs Act (Chapter 282 of the 1985 Revised Edition), and to make consequential amendments to certain other written laws.

Be it enacted by the President with the advice and consent of the Parliament of Singapore, as follows:

PART I

PRELIMINARY

Short title and commencement

1.—(1) This Act may be cited as the Health Products Act 2005.

(2) Except for Part XIV, section 79 and the Third Schedule, this Act shall come into operation on such date as the Minister charged with responsibility for health may, by notification in the *Gazette*, appoint.

(3) Part XIV, section 79 and the Third Schedule shall come into operation on such date as the Minister charged with responsibility for national development may, by notification in the *Gazette*, appoint.

Interpretation

2.—(1) In this Act, unless the context otherwise requires —

"adverse effect", in relation to a health product, means any debilitating, harmful, toxic or detrimental effect that the health product has been found to have or to be likely to have on the body or health of humans when such health product is used by or administered to humans;

"advertisement", in relation to a health product, means the publication, dissemination or conveyance of any information for the purpose of promoting, whether directly or indirectly, the sale or use of that health product by any means or in any form, including the following:

(*a*) publication in a newspaper, magazine, journal or other periodical;

(*b*) display of posters or notices;

(*c*) circulars, handbills, brochures, pamphlets, books or other documents;

(*d*) letters addressed to individuals or bodies corporate or unincorporate;

(*e*) photographs or cinematograph films; and

(*f*) sound broadcasting, television, the Internet or other media;

"analyst" means any person who is designated as an analyst by the Chief Executive under section 8;

"Appeal Advisory Committee" means an Appeal Advisory Committee established by the Minister under section 11;

"Authority" means the Health Sciences Authority established under section 3 of the Health Sciences Authority Act (Cap. 122C);

"Chief Executive" means the person appointed under section 15 of the Health Sciences Authority Act to be the Chief Executive of the Authority;

"clinical trial" means an investigation in respect of a health product that involves human subjects and that is intended to —

(*a*) discover or verify its clinical, pharmacological or pharmacodynamic effects;

(*b*) identify any adverse effects that may arise from its use;

(*c*) study its absorption, distribution, metabolism and excretion; or

(*d*) ascertain its safety or efficacy;

"efficacy", in relation to a health product that is a device, includes the ability of the device to properly perform the function for which it is intended;

"enforcement officer" means —

(*a*) the Chief Executive; or

(*b*) any officer of the Authority or any other person who is appointed by the Chief Executive under section 7 to be an enforcement officer for the purposes of this Act;

"health product" means any substance, preparation or device —

(*a*) that is represented for use by humans;

(*b*) that, whether because of its presentation or otherwise, is likely to be taken for use by humans; or

(*c*) that is included in a class of substance, preparation or device which is or is ordinarily intended for use by humans,

solely or principally for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose, such as —

(i) preventing, diagnosing, monitoring, treating, curing or alleviating any disease, disorder, ailment, injury, handicap or abnormal physical or mental state, or the symptoms thereof, in humans;

(ii) compensating for any injury or handicap in humans;

(iii) investigating, modifying or replacing any part of the human anatomy or any physiological process in humans;

(iv) testing the susceptibility of humans to any disease, disorder or ailment;

(v) influencing, controlling or preventing conception in humans;

(vi) testing for pregnancy in humans;

(vii) inducing anaesthesia in humans;

(viii) destroying or inhibiting micro-organisms that may be harmful to humans;

(ix) cleansing, fragrancing, deodorising, beautifying, preserving, improving, altering or restoring the complexion, skin, hair or teeth of humans; or

(x) otherwise promoting or preserving human health and well-being;

"importer's licence" means a licence authorising the holder thereof to import any health product;

"licence" means any licence issued by the Authority under this Act;

"manufacture", in relation to a health product, means to make, fabricate, produce or process the health product and includes —

(*a*) any process carried out in the course of so making, fabricating, producing or processing the health product; and

(*b*) the packaging and labelling of the health product before it is supplied;

"manufacturer's licence" means a licence authorising the holder thereof to manufacture any health product;

"packaging", in relation to a health product or an active ingredient, means the container and other packaging material in which the

health product or active ingredient is supplied, and includes any informational sheet or leaflet that accompanies the health product or active ingredient when it is being supplied;

"presentation", in relation to a health product, means the way in which the health product is presented for supply, and includes matters relating to the name of the health product, the labelling and packaging of the health product and any other informational material associated with the health product;

"prohibited substance" means a substance that is prescribed as a substance that is not to be contained at all in any health product or in any particular classification of health products;

"Register of Health Products" means the Register of Health Products caused to be maintained by the Authority under section 34;

"registered health product" means a health product currently registered under Part VII;

"registrant", in relation to a registered health product, means the person who applied for and obtained the registration of the health product under this Act;

"regulations" means regulations made under section 73;

"sample", in relation to any health product or active ingredient, includes a sample of the packaging of the health product or active ingredient;

"supply", in relation to a health product, means to transfer possession of the health product by any means whether or not for reward, and includes the following:

(*a*) to sell the health product, whether by retail, wholesale or auction;

(*b*) to expose or display the health product as an invitation to treat;

(*c*) to transfer possession of the health product by exchange, gift, lease, loan, hire or hire-purchase;

(*d*) to supply the health product in connection with —

(i) a contract for the provision of any goods or the performance of any service; or

(ii) any advertising, sponsorship or promotional activity;

(*e*) to supply the health product by way of administration to or application in any person in the course of any diagnosis, treatment or test;

(*f*) to offer, agree or attempt to supply the health product in any of the ways described in paragraphs (*a*) to (*e*) or to cause or permit the health product to be supplied; and

(*g*) to keep or possess the health product for the purpose of supplying it in any of the ways described in paragraphs (*a*) to (*f*);

"veterinarian" means a person who is licensed under section 53 of the Animals and Birds Act (Cap. 7) to treat, vaccinate or inoculate any animal or bird;

"wholesale", in relation to a health product, means any one or more of the following:

(*a*) supplying the health product to a person who obtains the health product for the purposes of supplying it again to some other person;

(*b*) supplying the health product to a person as a commercial sample in the normal course of a lawful trade;

(*c*) supplying the health product to a Government department or statutory body which requires the health product for the purposes of the public service or use in connection with the exercise of any statutory powers;

(*d*) supplying the health product to a person or an institution concerned with scientific education or research which requires the health product for the purpose of education or research;

(*e*) supplying the health product to a person who requires the health product for the purpose of enabling him to comply with any requirements made by, or in pursuance of, any written law with respect to the medical treatment of persons employed by that person in any business or trade carried out by that person;

(*f*) supplying the health product to a person who requires to use the health product, other than by way of administration to one or more persons, for the purpose of his business or trade;

(*g*) supplying the health product by export to a party outside Singapore;

"wholesaler's licence" means a licence authorising the holder thereof to supply any health product by wholesale.

(2) For the purposes of this Act —

(*a*) a health product is adulterated if it contains or has been mixed with any substance or ingredient that is not stated on its label as being one of its constituent substances or ingredients, except where —

(i) in the case of a registered health product, the substance is an inactive ingredient approved by the Authority; or

(ii) in the case of an unregistered health product, the substance is an inactive ingredient which is permitted as a food additive or flavouring agent according to the Codex Alimentarius or such other similar document as may be prescribed;

(*b*) a health product is counterfeit if —

(i) it is presented in such a manner as to resemble or pass off as a registered health product when in fact it is not; or

(ii) it is presented with any false information as to its manufacturer or origin;

(*c*) a health product is tampered with if it has been modified or interfered with in any way that affects, or could affect, the quality, safety or efficacy of the health product and the modification or interference has the potential to cause, or is done for the purpose of causing, injury or harm to any person using the health product; and

(*d*) a health product is unwholesome if —

(i) it has a strength which differs from, or a standard of purity or quality which falls below, that which is represented on its label;

(ii) any of its constituent substances or ingredients, as stated on its label, has been extracted or omitted from it;

(iii) it contains any prohibited substance or any substance in excess of the prescribed permitted concentration;

(iv) it consists in whole or in part of any filthy, putrid or decomposed substance;

(v) it has been manufactured or stored under unsanitary conditions;

(vi) it has been kept in a package which is composed in whole or in part of any substance which may render the contents injurious to health;

(vii) it has been packed with any substance so as to reduce the purity, quality, strength or beneficial properties that it would have had if it had not been so packed; or

(viii) it has passed its expected useful life as determined during the process of manufacturing or its expiry date as assigned by its manufacturer.

(3) For the purposes of this Act, a licence or registration is not in force during the period of its suspension.

Purposes of Act

3. The purposes of this Act are —

(*a*) to provide for the classification of health products in accordance with their different characteristics and uses;

(*b*) to provide the framework for a uniform approach for —

(i) the registration of health products; and

(ii) the regulation of the manufacture, import, supply, storage, presentation and advertisement of health products;

(*c*) to allow for each class of health product to be registered and regulated by reference to its formulation, composition, design specification, quality, safety and efficacy and within the framework provided by this Act; and

(*d*) to prescribe the standards for health products in relation to their formulation, composition, design specification, quality, safety, efficacy and presentation.

Act to apply to classified health products

4.—(1) This Act shall apply to the health products as classified and described in the first and second columns of the First Schedule to the extent prescribed in the third column thereof.

(2) The Minister may, after consultation with the Authority, by order published in the *Gazette* add to, amend or vary the classification and descriptions of health products set out in the First Schedule and the extent to which the provisions of this Act shall apply thereto.

(3) In prescribing the extent to which this Act shall apply to any health product classified and described in the First Schedule, the Minister may specify the provisions or any part of any provision of this Act that shall or shall not apply in relation to such health product.

Act not to apply to supply or use of registered health products for veterinary purposes

5. Except as provided in Part XIV, the provisions of this Act shall not apply in relation to —

(*a*) the supply, by a veterinarian or any other person, of any registered health product for veterinary purposes; or

(*b*) the use, by a veterinarian or any other person, of any registered health product for veterinary purposes.

PART II

ADMINISTRATION

Administration of Act

6. The Authority shall be responsible for the administration and enforcement of this Act (except for Part XIV) subject to the general and special directions of the Minister.

Appointment of enforcement officers

7.—(1) The Chief Executive may in writing appoint —

(*a*) any officer of the Authority; or

(*b*) with the approval of the Authority, any other person,

to be an enforcement officer for the purposes of this Act.

(2) Every enforcement officer, when exercising his powers and carrying out his duties under this Act, shall comply with such general or special directions as may, from time to time, be given to him by the Chief Executive.

(3) Every enforcement officer when exercising any powers under this Act shall, if not in uniform, declare his office and shall, on demand, produce to any person affected by the exercise of those powers such identification card as the Authority may direct to be carried by the enforcement officer when exercising such powers.

Designation of analysts

8. The Chief Executive may designate any suitably qualified person as an analyst to carry out any test, evaluation or analysis as may be necessary for the purpose of the administration and enforcement of this Act.

Enforcement officers and analysts deemed to be public officers

9. Every enforcement officer and analyst shall be deemed to be a public servant within the meaning of the Penal Code (Cap. 224).

Advisory Committees

10. The Authority may establish one or more Advisory Committees consisting of such persons as it thinks fit to appoint for the purpose of advising the Authority on such matters arising out of the administration and enforcement of this Act as are referred to them by the Authority.

Appeal Advisory Committees

11. The Minister may establish one or more Appeal Advisory Committees consisting of such persons as he thinks fit to appoint for the purpose of —

(*a*) assisting him in his determination of any appeal that is brought to him under this Act; and

(*b*) advising him on any matter arising from any such appeal.

PART III

MANUFACTURE AND IMPORT OF HEALTH PRODUCTS

Manufacture of health products

12.—(1) No person shall manufacture any health product unless —

(*a*) he holds a valid manufacturer's licence;

(*b*) the premises and facilities used for manufacturing the health product are approved by the Authority for such use under the licence; and

(*c*) the manufacture of the health product is carried out in accordance with the conditions of the licence and such requirements as may be prescribed.

(2) A manufacturer's licence does not authorise the holder thereof to supply any health product manufactured by him to any other person unless the health product so manufactured by him is a registered health product.

(3) No person shall manufacture any health product which is —

(*a*) an adulterated health product;

(*b*) a counterfeit health product; or

(*c*) an unwholesome health product.

(4) Any person who contravenes subsection (1) or (3) shall be guilty of an offence and shall be liable on conviction to be punished as follows:

(*a*) in the case of an offence under subsection (1) or (3)(*c*), to a fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both; and

(*b*) in the case of an offence under subsection (3)(*a*) or (*b*), to a fine not exceeding $100,000 or to imprisonment for a term not exceeding 3 years or to both.

(5) In a prosecution for an offence under subsection (3), it shall be a defence for the accused to prove that he had taken all such precautions and exercised all such due diligence as could reasonably be expected of him in the circumstances to ensure that the health product did not contravene that subsection.

Import of health products

13.—(1) No person shall import any health product unless —

(*a*) he holds a valid importer's licence;

(*b*) the import of the health product is carried out in accordance with the conditions of the licence and such requirements as may be prescribed; and

(*c*) the premises and facilities used for storing the health product upon its entry into Singapore are approved by the Authority for such use under the licence.

(2) An importer's licence does not authorise the holder thereof to supply any health product imported by him to any other person unless the health product so imported by him is a registered health product.

(3) No person shall import any health product which is —

(*a*) an adulterated health product;

(*b*) a counterfeit health product;

(*c*) a health product that has been tampered with; or

(*d*) an unwholesome health product.

(4) Any person who contravenes subsection (1) or (3) shall be guilty of an offence and shall be liable on conviction to be punished as follows:

(*a*) in the case of an offence under subsection (1) or (3)(*d*), to a fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both; and

(*b*) in the case of an offence under subsection (3)(*a*), (*b*) or (*c*), to a fine not exceeding $100,000 or to imprisonment for a term not exceeding 3 years or to both.

(5) In a prosecution for an offence under subsection (3), it shall be a defence for the accused to prove that —

(*a*) he —

(i) did not know;

(ii) had no reason to believe; and

(iii) could not, with reasonable diligence, have ascertained,

that the health product was in contravention of that subsection; and

(*b*) he had taken all such precautions and exercised all such due diligence as could reasonably be expected of him in the circumstances to ensure that the health product did not contravene that subsection.

PART IV

SUPPLY OF HEALTH PRODUCTS

Wholesaling of health products

14.—(1) No person shall supply any health product by wholesale unless —

(*a*) he holds a valid wholesaler's licence;

(*b*) the wholesale supply of the health product is carried out in accordance with the conditions of the licence and such requirements as may be prescribed; and

(*c*) the premises and facilities used for storing the health product for distribution are approved by the Authority for such use under the licence.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both.

Restriction on supply of unregistered health products

15.—(1) No person shall supply any health product unless —

(*a*) the health product is a registered health product; or

(*b*) if the health product is unregistered, the supply of that health product is approved by the Authority under subsection (2).

(2) The Authority may, subject to such conditions as it thinks fit, grant its approval for the supply of an unregistered health product for use in a clinical trial, in the treatment of any person, or for such other special purposes as the Authority thinks fit.

(3) An application for the approval of the Authority under subsection (2) shall be made in the prescribed manner by the person intending to supply the unregistered health product.

(4) Any person who contravenes subsection (1) or any condition attached to an approval granted under subsection (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both.

Prohibition against supply of health products that are adulterated, counterfeits, etc.

16.—(1) No person shall supply any health product which is —

(*a*) an adulterated health product;

(*b*) a counterfeit health product;

(*c*) a health product that has been tampered with; or

(*d*) an unwholesome health product.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to be punished as follows:

(*a*) in the case of an offence under subsection (1)(*d*), to a fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both; and

(*b*) in the case of an offence under subsection (1)(*a*), (*b*) or (*c*), to a fine not exceeding $100,000 or to imprisonment for a term not exceeding 3 years or to both.

(3) In a prosecution for an offence under subsection (1), it shall be a defence for the accused to prove that —

(*a*) he —

(i) did not know;

(ii) had no reason to believe; and

(iii) could not, with reasonable diligence, have ascertained,

that the health product was in contravention of that subsection; and

(*b*) he had taken all such precautions and exercised all such due diligence as could reasonably be expected of him in the

circumstances to ensure that the health product did not contravene that subsection.

Supply of health products to be carried out in accordance with prescribed requirements

17.—(1) No person shall supply any health product unless the supply of the health product is carried out in accordance with such requirements as may be prescribed.

(2) The requirements that may be prescribed for the purposes of subsection (1) include the following:

(*a*) that the supply of the health product should be carried out only under, and in accordance with the conditions of, a licence issued by the Authority;

(*b*) that the supply of the health product should be carried out only by certain specified persons;

(*c*) that the supply of the health product should be carried out only at certain specified premises;

(*d*) that the supply of the health product should or should not be carried out in any specified manner;

(*e*) that the health product be supplied only to certain specified persons and for certain specified purposes; and

(*f*) that proper records should be kept in relation to any supply made of the health product.

(3) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both.

Presentation of health products

18.—(1) No person shall supply any health product unless the presentation of the health product complies with such requirements as may be prescribed.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both.

PART V

ADVERTISEMENT OF HEALTH PRODUCTS

Advertisement of health products

19.—(1) No person shall advertise any health product or cause any health product to be advertised unless —

(*a*) the health product is a registered health product; and

(*b*) the advertisement does not in any way represent the registered health product as being usable for any purpose other than that for which it has been registered.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

False or misleading advertisement

20.—(1) No person shall advertise any health product or cause any health product to be advertised in a false or misleading way.

(2) For the purposes of subsection (1), an advertisement of a health product shall be taken to be false or misleading if —

(*a*) it falsely describes the health product or gives any false information concerning the health product; or

(*b*) it is likely to create an erroneous impression regarding the formulation, composition, design specification, quality, safety, efficacy or uses of the health product.

(3) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Further requirements for advertisement of health products

21.—(1) No person shall advertise any health product or cause any health product to be advertised unless the advertisement complies with and is undertaken in accordance with such requirements as may be prescribed.

(2) The requirements that may be prescribed for the purposes of subsection (1) include the following:

(*a*) that the advertisement should include or exclude any specified type of information;

(*b*) that the advertisement should not make certain types of claims about the health product;

(*c*) that the advertisement should be distributed or circulated only to certain classes of persons;

(*d*) that the advertisement should not appear in certain types of publications or media; and

(*e*) that the advertisement should be submitted to the Authority for approval before publication.

(3) Any person who contravenes subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Defences for persons in publishing trade

22. In any proceedings for an offence under section 19, 20 or 21, it shall be a defence for the person charged to prove that —

(*a*) he is a person whose business is to publish or arrange for the publication of advertisements and that he received the advertisement for publication in the ordinary course of business;

(*b*) he has no financial interest in the supply of the health product featured in the advertisement; and

(*c*) he did not know and had no reason to suspect that the publication of the advertisement would contravene the provisions of section 19, 20 or 21, as the case may be.

Corrective measures in relation to contravening advertisements

23.—(1) Where any person has advertised any health product or caused any health product to be advertised in contravention of section 19, 20 or 21, the Authority may order that person to do any or all of the following:

(*a*) to stop the advertisement with immediate effect;

(*b*) to take such measures as may be reasonable and necessary in the circumstances to remove the advertisements that have already been published;

(*c*) to publish a corrective advertisement in such manner and containing such information as may be specified by the Authority.

(2) The person to whom an order under subsection (1) is directed shall bear the costs and expenses arising from the taking of any measure that is required of him under the order.

(3) If a person to whom an order under subsection (1) is directed fails to comply with the order —

(*a*) he shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both; and

(*b*) the Authority may take such steps as it thinks reasonable and necessary to implement the requirements of the order and recover any costs and expenses reasonably incurred by it in so doing from that person.

(4) This section shall not affect the liability of any person for an offence under this Part.

PART VI

LICENCES

Issue and renewal of licences

24.—(1) An application for a licence shall be made to the Authority in such form and manner as the Authority may require and shall be accompanied by —

(*a*) such particulars, information, documents and samples as the Authority may require; and

(*b*) if required by the Authority, a statutory declaration by the applicant verifying any information contained in or relating to the application.

(2) The Authority may, upon receiving an application under subsection (1) —

(*a*) issue the licence to the applicant if —

(i) the applicant satisfies such requirements as may be prescribed for the issue of the licence; and

(ii) the Authority is satisfied that the issue of the licence to the applicant will not be contrary to the public interest; or

(*b*) refuse to issue the licence applied for.

(3) Where the Authority refuses to issue a licence to an applicant under subsection (2)(*b*), the Authority shall, if requested to do so by the applicant, state in writing the reasons for the refusal.

(4) Every licence shall be issued in such form and manner as the Authority may determine, and shall be valid for such period as the Authority may specify therein unless it is sooner revoked or suspended in accordance with the provisions of this Act.

(5) The Authority may attach such conditions to a licence as it thinks necessary for the purpose of ensuring that the best practices are adopted in the manufacture, import or supply (as the case may be) of a health product, and may from time to time vary such conditions by notice in writing given to the licensee.

(6) Any person who, in making an application for a licence —

(*a*) makes any statement or furnishes any document which he knows to be false or does not believe to be true; or

(*b*) by the intentional suppression of any material fact, furnishes information which is misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(7) Subsections (1) to (6) shall apply, with the necessary modifications, to an application for the renewal of a licence.

Variation of licence

25.—(1) A licensee may apply to the Authority for the variation of any condition attached to his licence.

(2) An application under subsection (1) shall be made to the Authority in such form and manner as the Authority may require and shall —

(*a*) set out the variation required and the reasons for the variation; and

(*b*) be accompanied by —

(i) such particulars, information, documents and samples as the Authority may require; and

(ii) if required by the Authority, a statutory declaration by the applicant verifying any information contained in or relating to the application.

(3) Where the Authority decides to vary the licence to which the application relates, it shall amend the licence or issue a new licence to the licensee as it considers appropriate.

(4) Any person who, in making an application under subsection (1) —

(*a*) makes any statement or furnishes any document which he knows to be false or does not believe to be true; or

(*b*) by the intentional suppression of any material fact, furnishes information which is misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Register of licensees

26.—(1) The Authority shall cause to be kept and maintained in such form and manner as it thinks fit a register of persons who have been issued with a licence under this Act.

(2) Any person may inspect such parts of the register as the Authority may determine and obtain extracts therefrom during such hours and subject to the payment of the prescribed fee.

(3) Any extract from or copy of an entry in the register shall be prima facie evidence of the information stated therein if the extract or copy is certified under the hand of the Chief Executive or an officer of the Authority duly authorised by the Chief Executive to be a true extract or copy.

(4) The Authority may, from time to time, prepare and publish in such form and manner as it thinks fit a list of all licensees.

Suspension and revocation of licence and cancellation of approval

27.—(1) The Authority may suspend or revoke a licence or cancel any approval granted by it under this Act if the Authority has reasonable grounds to believe that —

(*a*) the issue of the licence or the grant of the approval has been obtained by fraud or misrepresentation;

(*b*) the licensee or the person to whom the approval has been granted has contravened or is contravening —

(i) any provision of this Act;

(ii) any condition attached to the licence or approval; or

(iii) any other prescribed requirement;

(*c*) the licensee or the person to whom the approval has been granted no longer satisfies any of the prescribed requirements based on which the licence was issued or the approval was granted to him; or

(*d*) it is in the public interest to do so.

(2) The Authority may revoke a licence or cancel any approval granted by it under this Act if the licensee or the person to whom the approval has been granted applies to the Authority for the revocation of the licence or the cancellation of the approval, as the case may be.

(3) Before suspending or revoking a licence or cancelling an approval under subsection (1), the Authority shall —

(*a*) give to the person to whom the licence has been issued or the approval has been granted (hereafter referred to as the person concerned) notice in writing of its intention to do so; and

(*b*) in such notice, call upon the person concerned to show cause within such time as may be specified in the notice as to why the licence should not be suspended or revoked or the approval should not be cancelled.

(4) If the person concerned —

(*a*) fails to show cause within the period of time given or such extended period of time as the Authority may allow; or

(*b*) fails to show sufficient cause,

as to why the licence should not be suspended or revoked or as to why the approval should not be cancelled, the Authority shall give notice in writing to the person concerned of the date from which the suspension or revocation of the licence or the cancellation of the approval is to take effect.

Appeal

28.—(1) Any person who is aggrieved by —

(*a*) the refusal of the Authority to issue or renew a licence under section 24 or to grant any approval under this Act;

(*b*) any condition attached by the Authority to a licence under section 24; or

(*c*) the decision of the Authority to suspend or revoke a licence or to cancel an approval under section 27,

may, within such time as may be specified in the notice informing him of the refusal, suspension, revocation or cancellation, as the case may be, appeal in writing to the Minister whose decision shall be final.

(2) Before making a decision under subsection (1), the Minister may refer the matter to an Appeal Advisory Committee and, in making his decision, the Minister shall have regard to any report made to him by the Appeal Advisory Committee.

(3) Notwithstanding that any appeal under subsection (1) is pending —

(*a*) any condition attached by the Authority to a licence under section 24; or

(*b*) the decision of the Authority to suspend or revoke a licence or to cancel an approval under section 27,

shall take effect from the date specified by the Authority, unless the Minister otherwise directs.

PART VII

REGISTRATION OF HEALTH PRODUCTS

Health products to be registered according to classification in First Schedule

29.—(1) The Authority shall register health products under this Act in accordance with the classifications set out in the First Schedule.

(2) The Authority may —

(*a*) subdivide any classification of health products into such number of categories as it thinks fit; and

(*b*) when registering any health product under that classification, assign that health product into such category within that classification as the Authority thinks fit.

Registration of health products

30.—(1) An application for the registration of a health product shall —

(*a*) be made to the Authority in such form and manner as the Authority may require;

(*b*) state the classification (and, where applicable, the category within that classification) under which the applicant is seeking to have the health product registered; and

(*c*) be accompanied by —

(i) such particulars, information, documents and samples as the Authority may require; and

(ii) if required by the Authority, a statutory declaration by the applicant verifying any information contained in or relating to the application.

(2) The Authority shall not register any health product unless the health product complies with such requirements as may be prescribed.

(3) The Authority may register a health product under the classification and category stated in the application for its registration if the Authority is satisfied, after an evaluation of the health product under section 33, that

the health product is suitable for registration under that classification and category.

(4) If the Authority finds that a health product is not suitable for registration under the classification or category stated in the application, it may —

(*a*) recommend to the applicant that the health product be registered under a more suitable classification or category as determined by the Authority; or

(*b*) refuse to register the health product.

(5) If the applicant accepts the recommendation of the Authority under subsection (4)(*a*), the Authority shall, subject to the payment of the appropriate prescribed fee by the applicant, register the health product under the classification or category recommended by it.

(6) If the applicant does not wish to register the health product under the classification or category recommended by the Authority under subsection (4)(*a*), he may —

(*a*) within such time as the Authority may allow, submit such additional information, documents and samples to the Authority as the Authority may require in support of his application to have the health product registered under the classification or category stated in his application; or

(*b*) withdraw the application.

(7) Upon considering the additional information, documents and samples submitted by the applicant under subsection (6)(*a*), the Authority may do any of the following:

(*a*) register the health product under the classification and category stated in the application if it is satisfied that it is appropriate to do so;

(*b*) subject to the payment of the appropriate prescribed fee by the applicant, register the health product under the classification or category recommended by the Authority under subsection (4)(*a*) if the applicant is agreeable thereto; or

(*c*) refuse to register the health product.

(8) Upon registering a health product under this Act, the Authority shall assign a registration number to the health product and shall enter in the

Register of Health Products the prescribed information pertaining to that health product.

(9) Where the Authority refuses to register a health product under subsection (2), (4)(*b*) or (7)(*c*), the Authority shall, if requested to do so by the applicant, state in writing the reasons for the refusal.

(10) Any person who, in making an application for the registration of a health product —

(*a*) makes any statement or furnishes any document which he knows to be false or does not believe to be true; or

(*b*) by the intentional suppression of any material fact, furnishes information which is misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duration of registration

31. The registration of a health product under this Act shall remain in force for so long as —

(*a*) the registrant of the health product continues to pay to the Authority within the prescribed time, such retention fee as may be prescribed for the retention of the registration of the health product in the Register of Health Products; and

(*b*) the registration is not otherwise suspended or cancelled by the Authority under section 38(1).

Conditions of registration

32. The Authority may attach such conditions to the registration of a health product as it thinks necessary for ensuring the quality, safety or efficacy of the health product, and may from time to time vary such conditions by notice in writing given to the registrant of the health product.

Evaluation of health products

33.—(1) In order to ascertain that a health product is suitable for registration under this Act or for registration under any particular classification or category, the Authority may —

(*a*) subject samples of the health product to an evaluation by an analyst;

(*b*) require the applicant for the registration of the health product to send samples of the health product for evaluation by an analyst and thereafter submit the evaluation report to the Authority; or

(*c*) consider the evaluation report of any body or organisation, whether in Singapore or elsewhere, that has evaluated the health product.

(2) The evaluation of a health product shall include such tests and examination of the health product as the Authority thinks necessary to determine the following matters:

(*a*) whether the quality, safety or efficacy of the health product for the purposes for which it is to be used has been satisfactorily established;

(*b*) whether the presentation of the health product is appropriate, given its formulation, composition or design specification and intended use;

(*c*) whether the health product complies with such requirements as may have been prescribed in relation thereto; and

(*d*) such other matters relating to the health product as the Authority thinks relevant.

(3) The requirements that may be prescribed for the purposes of subsection (2)(*c*) include the following:

(*a*) that the health product should not have in its composition —

(i) any prohibited substance; or

(ii) any particular substance in excess of the prescribed permitted concentration; and

(*b*) that the manufacture of the health product —

(i) if carried out in Singapore, should comply with such requirements as may be prescribed; and

(ii) if carried out elsewhere, should comply with such standards that are acceptable to the Authority.

(4) In determining whether a health product complies with the standards referred to in subsection (3)(*b*)(ii), the Authority may consider such

evidence as it thinks sufficient from a relevant overseas authority establishing that the manufacture of the health product is of the acceptable standard.

(5) The costs of and incidental to the evaluation of a health product shall be borne by the applicant for the registration of the health product.

Register of Health Products

34.—(1) The Authority shall cause to be maintained in such form and manner as it thinks fit a Register of Health Products for the purpose of compiling information in relation to all registered health products.

(2) Any person may inspect such parts of the Register of Health Products as the Authority may determine and obtain extracts therefrom during such hours and subject to the payment of such fee as may be specified by the Authority.

(3) Any extract from or copy of an entry in the Register of Health Products shall be prima facie evidence of the information stated therein if the extract or copy is certified under the hand of the Chief Executive or an officer of the Authority duly authorised by the Chief Executive to be a true extract or copy.

(4) The Authority may, from time to time, prepare and publish in such form and manner as it thinks fit a list of all registered health products.

Reclassification or recategorisation of health products on application of registrant

35.—(1) The Authority may, upon the application of the registrant of a registered health product —

(*a*) transfer the health product from the classification or category under which it has been registered to another classification or category; and

(*b*) cause such amendments to be made in the Register of Health Products as may be necessitated by the reclassification or recategorisation of that health product.

(2) An application under subsection (1) for the reclassification or recategorisation of a registered health product shall —

(*a*) be made to the Authority in such form and manner as the Authority may require; and

(*b*) be accompanied by —

(i) such particulars, information, documents and samples as the Authority may require; and

(ii) if required by the Authority, a statutory declaration by the applicant verifying any information contained in or relating to the application.

(3) Upon the reclassification or recategorisation of a registered health product under this section, the registrant of the health product shall take such steps as may be specified by the Authority to secure the necessary changes to the presentation and advertisement of the health product so as to bring them in conformity with the new classification or categorisation of the health product.

(4) If the registrant of the health product fails to comply with subsection (3), he shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(5) Any person who, in making an application under subsection (1) for the reclassification or recategorisation of a registered health product —

(*a*) makes any statement or furnishes any document which he knows to be false or does not believe to be true; or

(*b*) by the intentional suppression of any material fact, furnishes information which is misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Power to reclassify or recategorise health products in absence of application by registrant

36.—(1) Where —

(*a*) the Authority is satisfied upon information received by it in respect of a registered health product that the health product should be transferred from the classification or category under which it has been registered to another classification or category; but

(*b*) the registrant of the health product has not made an application under section 35 for the health product to be so reclassified or recategorised,

the Authority may, subject to subsection (2), of its own volition reclassify or recategorise the health product and cause such amendments to be made in the Register of Health Products as may be necessitated by the reclassification or recategorisation of that health product.

(2) Before reclassifying or recategorising a registered health product under subsection (1), the Authority shall —

(*a*) give to the registrant of the health product notice in writing of its intention to do so; and

(*b*) in such notice, call upon the registrant, if he wishes, to show cause within such time as may be specified in the notice as to why the health product should not be reclassified or recategorised as intended by the Authority.

(3) If the registrant of the health product —

(*a*) is agreeable to the reclassification or recategorisation of the health product; or

(*b*) fails to show cause within the period of time given or such extended period of time as the Authority may allow, or fails to show sufficient cause as to why the health product should not be reclassified or recategorised as intended by the Authority,

the Authority shall give notice in writing to the registrant of the health product of the date from which the reclassification or recategorisation of the health product is to take effect.

(4) The Authority may also in the notice given under subsection (3) require the registrant of the health product to take such steps as may be specified by the Authority to secure the necessary changes to the presentation and advertisement of the health product so as to bring them in conformity with the new classification or categorisation of the health product.

(5) The registrant of a health product who fails to comply with any of the requirements attached under subsection (4) to a notice given to him under subsection (3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(6) Where the registrant of a health product does not wish to have the health product reclassified or recategorised as intended by the Authority under this section, he may apply to the Authority to cancel the registration of the health product.

Registrant to notify Authority of changes concerning registered health product

37.—(1) The registrant of a registered health product shall notify the Authority in the prescribed manner and within the prescribed time if there is any change to —

(*a*) the formulation, composition or design specification of the health product;

(*b*) the indications or contra-indications of the health product;

(*c*) the recommended use, dosage or manner of administration or application of the health product;

(*d*) the presentation of the health product; or

(*e*) any other prescribed matter in relation to the health product.

(2) A notification under subsection (1) shall be accompanied by —

(*a*) such particulars, information, documents and samples as the Authority may require; and

(*b*) if required by the Authority, a statutory declaration by the registrant of the registered health product verifying any information contained in or relating to the notification.

(3) Upon receiving a notification under subsection (1), the Authority may —

(*a*) amend the registration of the health product to reflect the change as stated in the notification; or

(*b*) if it thinks necessary, reclassify or recategorise the health product in accordance with section 36.

(4) In determining whether to exercise its power under subsection (3)(*a*) or (*b*), the Authority may, if it thinks fit having regard to the proposed change as notified to it under subsection (1), require an evaluation, in accordance with section 33, of samples of the health product as so changed, and the costs of and incidental to the evaluation shall be borne by the registrant of the health product.

(5) If the registrant of a health product —

(*a*) fails to comply with subsection (1); or

(*b*) in compliance or purported compliance with subsection (1), furnishes the Authority with any information or document which he knows is false or misleading,

he shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both

Suspension and cancellation of registration

38.—(1) The Authority may suspend or cancel the registration of a health product if the Authority has reasonable grounds to believe that —

(*a*) the registration has been obtained by fraud or misrepresentation;

(*b*) the registrant of the health product has contravened or is contravening —

(i) any provision of this Act;

(ii) any condition attached to the registration; or

(iii) any other prescribed requirement;

(*c*) the formulation, composition, design specification, quality, safety, or presentation of the health product has changed such as to render it unsuitable to continue to be registered;

(*d*) the health product no longer complies with a prescribed requirement; or

(*e*) it is necessary to so suspend or cancel the registration of the health product in the interest of public health and safety.

(2) The Authority may cancel the registration of a health product if the registrant of the health product fails to pay the prescribed retention fee referred to in section 31(*a*) within the prescribed time.

(3) The Authority may, upon the application of the registrant of a health product, cancel the registration of the health product.

(4) Before suspending or cancelling the registration of any health product under subsection (1) or (2), the Authority shall —

(*a*) give to the registrant of the health product notice in writing of its intention to do so; and

(*b*) in such notice, call upon the registrant of the health product to show cause within such time as may be specified in the notice as to why the registration of the health product should not be suspended or cancelled.

(5) If the registrant of the health product —

(*a*) fails to show cause within the period of time given or such extended period of time as the Authority may allow; or

(*b*) fails to show sufficient cause,

as to why the registration of the health product should not be suspended or cancelled, the Authority shall give notice in writing to the registrant of the health product of the date from which the suspension or cancellation of the registration of the health product is to take effect.

Appeal

39.—(1) Any person who is aggrieved by —

(*a*) the refusal of the Authority to register a health product under section 30;

(*b*) any condition attached by the Authority to the registration of a health product under section 32;

(*c*) the decision of the Authority to reclassify or recategorise a health product under section 36 or 37; or

(*d*) the decision of the Authority to suspend or cancel the registration of a health product under section 38,

may, within such time as may be specified in the notice informing him of the refusal, suspension, revocation or cancellation, as the case may be, appeal in writing to the Minister whose decision shall be final.

(2) Before making a decision under subsection (1), the Minister may refer the matter to an Appeal Advisory Committee and, in making his decision, the Minister shall have regard to any report made to him by the Appeal Advisory Committee.

(3) Notwithstanding that any appeal under subsection (1) is pending —

(*a*) any condition attached by the Authority to the registration of a health product under section 32;

(*b*) the decision of the Authority to reclassify or recategorise a health product under section 36 or 37; or

(*c*) the decision of the Authority to suspend or cancel the registration of a health product under section 38,

shall take effect from the date specified by the Authority, unless the Minister otherwise directs.

PART VIII

DUTIES OF MANUFACTURERS, IMPORTERS, ETC., OF HEALTH PRODUCTS

Application of this Part

40. The duties imposed by this Part on manufacturers, importers, suppliers and registrants of health products shall apply in addition to any other duty imposed on them under Part III, IV or VII, as the case may be.

Keeping of records

41.—(1) The Authority may require the manufacturer, importer, supplier or registrant of a health product —

(*a*) to keep such records as the Authority may determine in relation to the manufacture, import, supply, use or administration (as the case may be) of the health product; and

(*b*) to produce such records for the inspection by the Authority or an enforcement officer as and when required by the Authority.

(2) The records referred to in subsection (1) shall be kept in such form and manner and for such period as the Authority may stipulate, and shall contain such information in relation to the manufacture, import, supply, use or administration (as the case may be) of the health product as the Authority may require.

(3) Any person who fails to comply with any requirement under subsection (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) Any person who, in compliance or purported compliance with subsection (1)(*b*), furnishes the Authority or an enforcement officer with any record which he knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Furnishing of information or document regarding health product

42.—(1) The Authority may, by notice in writing, require the manufacturer, importer, supplier or registrant of a health product to furnish to the Authority, within such time and for such period as may be specified in such notice, any information or document which he has in his possession or which he is in a position to obtain regarding such health product.

(2) Any person who fails to comply with a notice given to him by the Authority under subsection (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(3) Any person who, in compliance or purported compliance with a notice given to him by the Authority under subsection (1), furnishes the Authority with any information or document which he knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Reporting of defects and adverse effects to Authority

43.—(1) Where the manufacturer, importer, supplier or registrant of a health product becomes aware of —

(*a*) any defect in the health product (as defined in subsection (6)); or

(*b*) any adverse effect that has arisen or can arise from the use of the health product,

it shall be the duty of such person to inform the Authority within the prescribed time of the defect or adverse effect.

(2) Where the Authority receives any information under subsection (1) concerning any defect in, or adverse effect of, a health product or becomes aware of any such defect or adverse effect through any other means, it may take any one or more of the following actions:

(*a*) by order require the manufacturer, importer, registrant or supplier of the health product to investigate into the defect or adverse effect and make a report of his findings and recommendations to the Authority;

(*b*) by order require the manufacturer, importer, registrant or supplier of the health product to cause to be given to such persons as the Authority may specify or to the general public, a notice informing them of the defect or adverse effect and the measures that should be taken for addressing such defect or adverse effect;

(*c*) by order require the manufacturer, importer, registrant or supplier of the health product to take such measures as the Authority may specify to secure the immediate stoppage of the manufacture, import, supply, use or administration (as the case may be) of the health product;

(*d*) by order prohibit any person from using or administering health product and require such person to take such measures as the Authority may specify to address any adverse effect that may have arisen from any previous use or administration of the health product;

(*e*) by order require the manufacturer, importer, registrant or supplier of the health product to take such other measures as the Authority thinks necessary in the circumstances.

(3) The Authority may also in an order given under subsection (2) require the person to whom the order has been given to submit to the Authority in such form and manner and within such time and for such period as the Authority may specify, a report containing information on —

(*a*) the measures that he has taken under the order;

(*b*) the results of the measures so taken; and

(*c*) any other matter as the Authority thinks necessary or relevant in the circumstances.

(4) A notice under subsection (2)(*b*) shall be given in such form and manner as the Authority may require, including by publication in all daily newspapers in Singapore or by dissemination in such alternative medium within such time and for such period as the Authority may determine.

(5) Any person who —

(*a*) fails to comply with subsection (1) or an order given to him by the Authority under subsection (2) or (3); or

(*b*) in compliance or purported compliance with subsection (1) or an order given to him by the Authority under subsection (2) or (3), furnishes the Authority with any information or document which he knows is false or misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(6) For the purposes of this section, a health product has a defect if —

(*a*) it has been adulterated or tampered with;

(*b*) it is a counterfeit or an unwholesome health product;

(*c*) it is of inadequate quality or is unsafe or inefficacious for its intended use; or

(*d*) it fails to satisfy such other standards or requirements as may be prescribed.

Verification of quality, safety and efficacy of health product

44.—(1) Where the Authority has reasonable grounds to believe that a health product may no longer be of adequate quality, safe or efficacious when used for the purpose in respect of which it has been registered under this Act, the Authority may, by notice in writing, require the manufacturer, importer, supplier or registrant of the health product to take such measures as the Authority may specify to verify the quality, safety or efficacy (as the case may be) of the health product.

(2) The measures that the Authority may require under subsection (1) include —

(*a*) subjecting the health product to an evaluation in accordance with section 33; and

(*b*) furnishing the Authority with such evidence of the quality, safety or efficacy of the health product as the Authority may require.

(3) Any person who fails to comply with a notice given to him by the Authority under subsection (1) shall be guilty of an offence and shall be

liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) Any person who, in compliance or purported compliance with a notice given to him by the Authority under subsection (1), furnishes the Authority with any information or document which he knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Notification to Authority concerning recall of health product

45.—(1) Where the manufacturer, importer, supplier or registrant of a health product recalls the health product, he shall, before commencing the recall or, if that is not possible, within the prescribed time from the commencement of the recall, notify the Authority of the recall and the reasons therefor.

(2) Any person who —

(*a*) fails to comply with subsection (1); or

(*b*) in compliance or purported compliance with subsection (1), furnishes the Authority with any information or document which he knows is false or misleading,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Additional duties under regulations

46. The Minister may, after consultation with the Authority, by regulations provide for such additional duties as he thinks fit to be imposed on manufacturers, importers, suppliers and registrants of health products.

PART IX

REGULATION OF DEALINGS IN ACTIVE INGREDIENTS

Active ingredient

47. For the purposes of this Part, an active ingredient is a substance or compound that —

(*a*) is usable in the manufacture of a health product as a pharmacologically active ingredient; and

(*b*) is prescribed to be an active ingredient to which this Part applies.

Regulation of manufacture, import, supply, etc., of active ingredients

48.—(1) The Minister may, after consultation with the Authority, make regulations to control and regulate the manufacture, import, supply, transport, possession and storage of active ingredients.

(2) Regulations made under subsection (1) may —

(*a*) prohibit the manufacture, import, supply, transport, possession or storage of any active ingredient except under and in accordance with the conditions of a licence issued by the Authority; and

(*b*) prescribe the requirements to be complied with by any person who manufactures, imports, supplies, transports, possesses or stores any active ingredient.

(3) The requirements that may be prescribed for the purposes of subsection (2)(*b*) include the following:

(*a*) that the manufacture, import, supply, transport or storage of any active ingredient should be carried out only by certain specified persons;

(*b*) that the manufacture, supply or storage of any active ingredient should be carried out only at certain specified premises;

(*c*) that the manufacture, import, supply, transport or storage of any active ingredient should or should not be carried out in any specified manner;

(*d*) that the packaging of any active ingredient should comply with certain standards or specifications;

(*e*) that the labels on the packaging of any active ingredient should conform to certain specifications and contain certain specified information;

(*f*) that the supply of any active ingredient should only be made to certain specified persons and for certain specified purposes; and

(*g*) that proper records should be kept in relation to any supply made of any active ingredient.

(4) Any person who contravenes any regulation made under this section shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $50,000 or to imprisonment for a term not exceeding 2 years or to both.

(5) In any proceedings for an offence under subsection (4), if any person is proved to have kept or had in his possession or under his control any active ingredient, he shall be deemed to have done so knowingly unless the contrary is proved by him.

PART X

ENFORCEMENT

Non-compliant health products and active ingredients

49. For the purposes of this Part —

(*a*) a health product shall be considered as being non-compliant if —

(i) it has been manufactured, imported or supplied in contravention of this Act;

(ii) it is an adulterated health product, a counterfeit health product, a health product that has been tampered with or an unwholesome health product; or

(iii) it does not comply with such requirements as may be prescribed in relation to it; and

(*b*) an active ingredient shall be considered as being non-compliant if —

(i) it has been manufactured, imported or supplied in contravention of this Act; or

(ii) it does not comply with such requirements as may be prescribed in relation to it.

Powers of enforcement

50.—(1) For the purpose of the administration and enforcement of this Act, an enforcement officer may —

(*a*) at any time and without warrant enter, inspect and search any premises that are being used, or that the enforcement officer has reason to suspect are being used, for or in connection with any purpose that is in contravention of this Act;

(*b*) at any time and without warrant stop, board, inspect and search any conveyance that is being used, or that the enforcement officer has reason to suspect is being used, for or in connection with any purpose that is in contravention of this Act;

(*c*) in accordance with such procedure as may be prescribed and without payment, take for testing, examination or analysis a sample of any health product or active ingredient that is found pursuant to an inspection or a search under paragraph (*a*) or (*b*);

(*d*) seize —

(i) any health product or active ingredient, wherever found, if the enforcement officer knows or has reason to suspect that the health product or active ingredient is a non-compliant health product or active ingredient; or

(ii) any other substance or article which the enforcement officer has reasonable cause to believe to be a substance or an article in relation to which, or by means of which, an offence under this Act is being or has been committed;

(*e*) require by notice in writing any person to attend at such reasonable time and at such place as may be specified by the enforcement officer to answer any question or to provide a signed statement in writing concerning any suspected contravention of this Act;

(*f*) arrest, without warrant, any person whom the enforcement officer has reason to believe has committed any offence under this Act if —

(i) the name and address of that person are unknown;

(ii) the person refuses to furnish his name or address;

(iii) the person furnishes an address out of Singapore;

(iv) the enforcement officer has reasonable grounds for believing that the person has furnished a false name or address; or

(v) the enforcement officer has reasonable grounds for believing that the person is likely to abscond;

(*g*) require any person —

(i) to furnish any information within his knowledge; or

(ii) to produce for inspection any document or record within his possession,

that the enforcement officer believes on reasonable grounds to be connected with any suspected contravention of this Act or to be otherwise relevant to the administration or enforcement of this Act;

(*h*) retain the original copy of any document or record that the enforcement officer believes on reasonable grounds to be connected with any suspected contravention of this Act or to be otherwise relevant to the administration or enforcement of this Act, or make or cause to be made, without payment, copies of or extracts from such document or record; and

(*i*) require by notice in writing any person having in his possession any health product or active ingredient that is intended for supply to submit, at his own expense, a sample of such health product or active ingredient to an analyst for analysis.

(2) In exercising his power under subsection (1)(*a*) or (*b*), an enforcement officer may —

(*a*) require the owner or occupier of any premises or conveyance being inspected to provide all reasonable assistance to the enforcement officer for the purpose of the inspection; and

(*b*) if the circumstances so warrant, with such assistance as he thinks necessary, break open any door, window, lock, fastener, hold, compartment, box, container, receptacle or any other thing,

and any person who fails to comply with any requirement of an enforcement officer under paragraph (*a*) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(3) The Authority may, by notice in writing, require any person who has supplied any health product or active ingredient to recall, within such period as may be specified in the notice, all such health product or active ingredient if the Authority knows or has reason to believe that such health product or active ingredient is a non-compliant health product or active ingredient.

(4) The Authority may, by notice in writing, require any person who manufactures, imports or supplies any health product or active ingredient to cease (whether immediately or within such time as the Authority may specify) the manufacture, import or supply of such health product or active ingredient if —

(*a*) the Authority knows or has reason to believe that such health product or active ingredient is a non-compliant health product or active ingredient; or

(*b*) a sample of the health product or active ingredient has been taken or obtained under subsection (1)(*c*) or (*i*) and sent for analysis and pending the result of the analysis, the Authority is of the opinion that it is necessary to prevent any more of such health product or active ingredient from further being manufactured, imported or supplied.

(5) Where any item is seized under subsection (1)(*d*) —

(*a*) the enforcement officer making such seizure shall immediately give notice in writing of the seizure to the person from whom the item is seized, if his name and address are known;

(*b*) any person claiming the item seized may within 48 hours after the seizure complain thereof to a Magistrate, and the complaint may be heard and determined by the Magistrate who may —

(i) confirm the seizure wholly or in part;

(ii) disallow the seizure wholly or in part;

(iii) order that the item seized be restored to its owner, subject to such condition which the Magistrate may think fit to impose

to ensure that the item is preserved for any purpose for which it may subsequently be required; or

(iv) order payment to be made to the owner of the item seized of such amount as the Magistrate considers will compensate him for any loss or depreciation resulting from the seizure;

(*c*) in the absence of any claim under paragraph (*b*) or pending the determination of any such claim, the item may be kept or stored in the premises or conveyance where it was seized or may, at the direction of the enforcement officer, be removed to any other place to be kept or stored thereat;

(*d*) the enforcement officer may —

(i) mark, seal or label the item in such manner as he thinks fit for the purpose of indicating that the item is under detention; and

(ii) lock or seal the premises or conveyance in which the item is being detained; and

(*e*) any person who, without the authority of the enforcement officer —

(i) interferes, tampers with, removes, distributes, sells or otherwise disposes of the item;

(ii) alters, counterfeits, defaces, destroys, erases or removes any mark, seal or label placed by the enforcement officer on the item under paragraph (*d*)(i); or

(iii) opens, breaks or otherwise tampers with the lock or seal placed by the enforcement officer on any premises or conveyance or part thereof under paragraph (*d*)(ii),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(6) No person arrested under subsection (1)(*f*) shall be detained longer than is necessary for bringing him before a court unless the order of a court for his detention is obtained.

(7) For the purposes of subsection (1)(*g*), where any document or record required by an enforcement officer is kept in electronic form, then —

(*a*) the power of the enforcement officer to require any such documents or records to be produced for inspection includes power to require a copy of the documents or records to be made available for inspection in legible form (and subsection (1)(*h*) shall accordingly apply in relation to any copy so made available); and

(*b*) the power of the enforcement officer to inspect such document or record includes the power to require any person on the premises in question to give the enforcement officer such assistance as the enforcement officer may reasonably require to enable him —

(i) to inspect and make copies of the document or record in legible form or to make records of the information contained therein; or

(ii) to inspect and check the operation of any computer, and any associated apparatus or material, that is or has been in use in connection with the keeping of the document or record.

(8) Any copy of or extract from any document made under subsection (1)(*h*) and certified as such by the enforcement officer shall be admissible as evidence in any proceedings under this Act or the regulations.

(9) Any person who, when required by an enforcement officer under subsection (1)(*g*) to furnish any information or produce any document or record, refuses or fails, without reasonable excuse, to furnish the information or to produce the document or record within the time allowed by the enforcement officer shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(10) Any person who, when required by an enforcement officer —

(*a*) under subsection (1)(*e*) to answer any question or to provide any signed statement in writing; or

(*b*) under subsection (1)(*g*) to furnish any information or produce any document or record,

in compliance or purported compliance with such requirement, furnishes the enforcement officer with any information, document or record which he knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(11) Any person who fails, without reasonable excuse, to comply with any notice in writing given to him —

(*a*) by an enforcement officer under subsection (1)(*e*) or (*i*); or

(*b*) by the Authority under subsection (3) or (4),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

Unlawful alteration, destruction, etc., of documents

51. Any person who alters, suppresses, conceals or destroys any document which he is or is liable to be required, by or under this Act, to produce to an enforcement officer shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Obstructing officers in execution of their duties

52. Any person who obstructs, hinders or impedes any enforcement officer or any other person acting under the direction of the Authority or its Chief Executive in the performance or execution of his duty or anything which he is authorised, empowered or required to do under this Act shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

PART XI

PRESUMPTIONS AND OTHER EVIDENTIARY PROVISIONS FOR PURPOSES OF ENFORCEMENT OF ACT

Presumption as to liability of importers and manufacturers

53. Where any health product or active ingredient is supplied in a package, any person who appears from any statement thereon or attached thereto to have imported or manufactured that health product or active ingredient shall, until the contrary is proved, be presumed to have so imported or manufactured the health product or active ingredient.

Presumption as to identity of advertiser

54. Where any health product is advertised, the person whose name or particulars appear in the advertisement shall, until the contrary is proved, be presumed to be the person who has advertised the health product.

Presumption as to purpose for which health product is manufactured, imported or supplied

55.—(1) Any person who manufactures, imports or supplies any health product shall be presumed, until the contrary is proved, to have manufactured, imported or supplied the health product for use by humans.

(2) Any health product that is found —

(*a*) on any premises that are used for the manufacture, storage or supply of health products;

(*b*) in any conveyance that is used for the transportation of health products; or

(*c*) in any automatic vending machine,

shall be presumed, until the contrary is proved, to be intended for use by humans.

Presumption as to similarity in properties between health products, etc., found and sample taken therefrom

56. Any quantity of a health product or an active ingredient found in or on any premises or conveyance at the time when a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample.

Presumption of person's intention to supply health product found in his possession

57. Where any person is found to be keeping or to be in possession of any health product in circumstances in which it would be reasonable to suspect that he intends to supply the health product, he shall be presumed, until the contrary is proved, to have the health product in his possession for the purpose of supply.

Evidence of analyst

58.—(1) Subject to subsection (2), the certificate of an analyst stating that he has tested, examined or analysed any health product, active ingredient or other substance or thing and stating the result of his test, examination or analysis shall be admissible in evidence in any proceedings for an offence under this Act as prima facie evidence of the facts stated in the certificate and of the correctness of the result of the test, examination or analysis.

(2) The certificate of an analyst referred to in subsection (1) shall not be received in evidence in pursuance of that subsection unless the person charged has been given a copy of the certificate together with reasonable notice of the intention of the prosecution to produce the certificate as evidence in the proceedings.

(3) Where a certificate of an analyst is admitted in evidence under subsection (1), the person charged may require the analyst to be called as a witness for the prosecution and the analyst may be cross-examined as if he had given evidence of the matters stated in the certificate.

(4) For the purposes of this section, a document purporting to be a certificate referred to in subsection (1) on its production by the prosecution shall, unless the contrary is proved, be deemed to be such a certificate.

PART XII

OFFENCES AND PROSECUTION

Jurisdiction of court

59. Notwithstanding any provision to the contrary in the Criminal Procedure Code (Cap. 68), a District Court shall have jurisdiction to try any offence under this Act and shall have power to impose the full penalty or punishment in respect of the offence.

Offences by bodies corporate, etc.

60.—(1) Where an offence under this Act committed by a body corporate is proved —

(*a*) to have been committed with the consent or connivance of an officer; or

(*b*) to be attributable to any neglect on his part,

the officer as well as the body corporate shall be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, subsection (1) shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(3) Where an offence under this Act committed by a partnership is proved —

(*a*) to have been committed with the consent or connivance of a partner; or

(*b*) to be attributable to any neglect on his part,

the partner as well as the partnership shall be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

(4) Where an offence under this Act committed by an unincorporated association (other than a partnership) is proved —

(*a*) to have been committed with the consent or connivance of an officer of the unincorporated association or a member of its governing body; or

(*b*) to be attributable to any neglect on the part of such an officer or member,

the officer or member as well as the unincorporated association shall be guilty of the offence and shall be liable to be proceeded against and punished accordingly.

(5) In this section —

"officer" —

(*a*) in relation to a body corporate, means any director, member of the committee of management, chief executive, manager, secretary or other similar officer of the body corporate and includes any person purporting to act in any such capacity; or

(*b*) in relation to an unincorporated association (other than a partnership), means the president, the secretary, or any member of the committee of the unincorporated association, or any person holding a position analogous to that of

president, secretary or member of a committee and includes any person purporting to act in any such capacity;

"partner" includes a person purporting to act as a partner.

(6) Regulations may provide for the application of any provision of this section, with such modifications as the Authority considers appropriate, to any body corporate or unincorporated association formed or recognised under the law of a territory outside Singapore.

Enhanced penalty for corporations

61. Where a body corporate is convicted of an offence under this Act, the penalty that the court may impose shall be a fine not exceeding 2 times the maximum amount that the court could, but for this section, impose as a fine for that offence.

Liability for offences by agents or servants

62. Where an offence under this Act is committed by any person acting as an agent or servant of another person, or being otherwise subject to the supervision or instruction of another person for the purposes of any employment in the course of which the offence was committed, that other person shall, without prejudice to the liability of the first-mentioned person, be liable under this Act in the same manner and to the same extent as if he had personally committed the offence if it is proved that the act which constituted the offence was committed with his consent or connivance or that it was attributable to any neglect on his part.

Forfeiture

63.—(1) The court before which any person is tried for an offence under this Act may make an order for the forfeiture of any item which has been seized under the provisions of this Act if the court is satisfied that —

(*a*) an offence under this Act has been committed; and

(*b*) the item seized was the subject-matter, or was used in the commission, of the offence.

(2) Where no party raises the question of forfeiture under subsection (1), the court may consider the question on its own motion.

(3) The court may make an order under subsection (1) for the forfeiture of any item which has been seized under the provisions of this Act notwithstanding that no person have been convicted of an offence.

(4) If the court, having regard to the circumstances of the case, does not think it fit to order the forfeiture of any item which has been seized under the provisions of this Act, the court shall order that the item be released to the owner thereof or the person entitled thereto.

(5) If —

(*a*) no prosecution is instituted with regard to any item which has been seized under the provisions of this Act; and

(*b*) no claim is made for the item under section 50(5)(*b*),

the item to which the notice relates shall be deemed to be forfeited.

(6) Where the owner of any item seized under the provisions of this Act consents to its disposal, the item shall thereupon be deemed to be forfeited.

(7) Any item forfeited or deemed to be forfeited under this section shall be delivered to an authorised officer and shall be disposed of in such manner as the Chief Executive thinks fit.

(8) The cost of the disposal of the item under subsection (7) shall be borne by the owner of that item.

Recovery of fees and other expenses incidental to prosecution

64.—(1) When any person is convicted of an offence under this Act, the court may order that person to pay the following costs and expenses:

(*a*) all expenses incidental to the analysis of any health product or active ingredient in respect of which the conviction is obtained;

(*b*) the cost of the purchase of any sample of the health product or active ingredient for analysis; and

(*c*) any other reasonable expenses incurred by the prosecution.

(2) If the amount of costs and expenses are not paid by the person liable to pay within 14 days after demand, that amount may be reported to a Magistrate's Court and recovered in the same manner as if it were a fine imposed by a Magistrate's Court.

Non-disclosure of information

65.—(1) No prosecutor or witness in any prosecution of an offence under this Act shall be compelled to disclose the fact that he received any

information or the nature of the information or the name of any person who gave the information.

(2) No officer appearing as a prosecutor or witness in connection with any offence under this Act shall be compelled to produce any confidential report or document made or received by him in his official capacity or to make any statement in relation thereto.

Composition of offences

66.—(1) The Chief Executive or any officer of the Authority authorised in writing in that behalf by the Chief Executive may, in his discretion, compound any offence under this Act which is prescribed as a compoundable offence by collecting from a person reasonably suspected of having committed the offence a sum not exceeding —

(*a*) one-half of the amount of the maximum fine that is prescribed for the offence; or

(*b*) $5,000,

whichever is the lower.

(2) On payment of such sum, no further proceedings shall be taken against such person in respect of the offence.

PART XIII

MISCELLANEOUS

Protection of confidential information

67.—(1) Except as otherwise provided in subsection (2), no person who is or has been involved in the administration and enforcement of this Act shall disclose any information relating to any health product that he knows or ought reasonably to know to be confidential information.

(2) Nothing in subsection (1) shall prevent any person from disclosing any information within his knowledge concerning any health product where such disclosure is made —

(*a*) with the permission of the person from whom the information was obtained;

(*b*) for the purpose of the administration and enforcement of this Act;

(*c*) for the purpose of assisting any public officer or officer of any other statutory board in the investigation or prosecution of any offence under any written law;

(*d*) for such other prescribed purpose; or

(*e*) in compliance with the requirement of any court or the provisions of any written law.

(3) For the purpose of this section, the reference to a person disclosing or making use of any information includes his permitting any other person to have any access to any record, document or other thing which is in his possession or under his control by virtue of his being or having been involved in the administration or enforcement of this Act.

(4) Any person who contravenes subsection (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Service of documents

68.—(1) Any notice, order or document required or authorised by this Act to be served on any person, and any summons issued by a court against any person in connection with any offence under this Act may be served on the person —

(*a*) by delivering it to the person or to some adult member or employee of his family or household at his last known place of residence;

(*b*) by leaving it at his usual or last known place of residence or business in an envelope addressed to the person;

(*c*) by sending it by registered post addressed to the person at his usual or last known place of residence or business; or

(*d*) in the case of an incorporated company, a partnership or a body of persons —

(i) by delivering it to the secretary or other like officer of the company, partnership or body of persons at its registered office or principal place of business; or

(ii) by sending it by registered post addressed to the company, partnership or body of persons at its registered office or principal place of business.

(2) Any notice, order, document or summons sent by registered post to any person in accordance with subsection (1) shall be deemed to be duly served on the person at the time when the notice, order, document or summons, as the case may be, would in the ordinary course of post be delivered and, in proving service of the notice, order, document or summons, it shall be sufficient to prove that the envelope containing the same was properly addressed, stamped and posted by registered post.

Form and authentication of notices, orders and other documents

69.—(1) All notices, orders and other documents which an enforcement officer is empowered to give by this Act may be in such form and manner as the Chief Executive may determine, and may be given by any enforcement officer.

(2) Where any such notice, order or document requires authentication —

(*a*) the signature of the Chief Executive or an enforcement officer; or

(*b*) an official facsimile of such signature,

appended thereto shall be sufficient authentication.

Inaccuracies in documents

70.—(1) No misnomer or inaccurate description of any person, premises, conveyance or any other thing named or described in any notice, order or document prepared, issued or served under or for the purposes of this Act shall in any way affect the operation of this Act as respects that person, premises, conveyance or thing if that person, premises, conveyance or thing is so designated or described in the notice, order or document as to be identifiable.

(2) No proceedings taken under or by virtue of this Act shall be invalid for want of form.

Exemption

71.—(1) Subject to any general or special direction of the Minister, the Authority may, by order in the *Gazette*, exempt any person or class of

persons or any health product or class of health products from all or any of the provisions of this Act.

(2) In granting an exemption under subsection (1), the Authority may impose such conditions as it thinks fit.

(3) An exemption granted under this section may be revoked at any time.

Fees

72.—(1) The Authority may, with the approval of the Minister, make regulations to prescribe the fees that are payable under and for the purposes of this Act and the time at which and the manner in which any such fee is to be paid.

(2) All fees collected under this Act shall be paid into the fund of the Authority.

Regulations

73.—(1) The Minister may, after consultation with the Authority, make regulations for carrying out the purposes and provisions of this Act.

(2) Without prejudice to the generality of subsection (1), the Minister may, after consultation with the Authority, make regulations for or with respect to all or any of the matters set out in the Second Schedule, and provide in such regulations that a contravention thereof shall be an offence punishable with a fine not exceeding $20,000 or with imprisonment for a term not exceeding 12 months or with both.

(3) Regulations made under this section in relation to the supply or use of health products shall not affect the supply or use of health products for veterinary purposes.

(4) Regulations made pursuant to paragraph 1(*l*) of the Second Schedule for implementing any international agreement to which Singapore is a party shall have effect notwithstanding any written law or rule of law to the contrary.

(5) All regulations made under this section shall be presented to Parliament as soon as possible after publication in the *Gazette*.

PART XIV

REGULATION OF SUPPLY AND USE OF REGISTERED HEALTH PRODUCTS AND ACTIVE INGREDIENTS FOR VETERINARY PURPOSES

Supply and use of registered health products for veterinary purposes

74.—(1) The Minister charged with responsibility for national development may, after consultation with the Agri-Food and Veterinary Authority (established under the Agri-Food and Veterinary Authority (Cap. 5)), make regulations in relation to the supply and use of registered health products or active ingredients for veterinary purposes.

(2) Regulations made under subsection (1) may —

(*a*) prohibit the supply or use of any registered health product or active ingredient for any veterinary purpose, whether absolutely or subject to such exceptions as may be prescribed;

(*b*) require that the supply or use of any registered health product or active ingredient for veterinary purposes should be made only in accordance with the prescription of a veterinarian;

(*c*) provide for such other restrictions or controls on the use of any registered health product or active ingredient for veterinary purposes;

(*d*) provide that a contravention thereof shall be an offence punishable with a fine not exceeding $20,000 or with imprisonment for a term not exceeding 12 months or with both; and

(*e*) provide for the administration and enforcement of such regulations by officers of the Agri-Food and Veterinary Authority.

(3) All regulations made under this section shall be presented to Parliament as soon as possible after publication in the *Gazette*.

Powers of officers enforcing regulations made under section 74

75. An officer of the Agri-Food and Veterinary Authority administering and enforcing any regulations made under section 74 shall have the same powers as are conferred on an enforcement officer by section 50.

Application of Parts X to XIII

76. The provisions of Parts X to XIII shall, where relevant, apply with the following modifications to the administration and enforcement of any regulations made under section 74:

(*a*) any reference in the provisions of those Parts to the Minister shall be read as a reference to the Minister charged with responsibility for national development;

(*b*) any reference in the provisions of those Parts to the Authority shall be read as a reference to the Agri-Food and Veterinary Authority (Cap. 5);

(*c*) any reference in the provisions of those Parts to the Chief Executive shall be read as a reference to the Chief Executive of the Agri-Food and Veterinary Authority; and

(*d*) any reference in the provisions of those Parts to an enforcement officer shall be read as a reference to an officer of the Agri-Food and Veterinary Authority who is acting in the administration and enforcement of such regulations.

PART XV

PROVISIONS FOR TRANSFERRING REGULATION OF MEDICINAL PRODUCTS FROM MEDICINES ACT TO THIS ACT

Amendment of Medicines Act

77. The Medicines Act (Cap. 176) is amended by inserting, immediately after section 76, the following section:

"**Act not to apply to products upon being classified and regulated as health products under Health Products Act 2005**

77.—(1) Where any product to which this Act applies has been classified as a type of health product under the Health Products Act 2005, the Minister may, by order published in the *Gazette*, declare that the provisions of this Act shall cease to apply to that type of product as from the date specified in the order, and the provisions of this Act shall, as from the date so specified, cease to apply to that type of product.

(2) The Minister may, in making any order under subsection (1), prescribe such transitional, savings and other consequential provisions as he may consider necessary or expedient.".

Repeal of Medicines Act

78. The Medicines Act (Cap. 176) is repealed.

Consequential amendments to Animals and Birds Act

79. The Animals and Birds Act (Cap. 7) is amended —

(*a*) by inserting, immediately after the words "animals, birds or fish in Singapore" in the long title, the words "; for the regulation of dealings in veterinary health products,";

(*b*) by deleting the definition of "veterinary biologics" in section 2;

(*c*) by deleting the words "animal, bird or veterinary biologics" in section 8(1) and (2) and section heading and substituting in each case the words "animal or bird";

(*d*) by deleting the words "an animal, bird or veterinary biologics" in section 8(3) and substituting the words "an animal or a bird";

(*e*) by deleting the words ", VETERINARY BIOLOGICS" in the heading to Part VII;

(*f*) by deleting section 55;

(*g*) by inserting, immediately after section 59, the new Part VIIIA as set out in the Third Schedule; and

(*h*) by inserting, immediately after the word "bird," wherever it appears in section 76(1), the word "article,".

Consequential amendments to certain other written laws

80.—(1) Section 14(1) of the Pharmacists Registration Act (Cap. 230) is amended by inserting, immediately after the words "this Act," in paragraph (*b*), the words "the Health Products Act 2005,".

(2) The provisions of the Acts specified in the first column of the Fourth Schedule are amended by deleting the words as specified in the second column of that Schedule and substituting, in each case, the appropriate words as may be prescribed under subsection (3).

(3) For the purpose of bringing the provisions of the Acts as specified in the first column of the Fourth Schedule into conformity with the classification of medicinal products as a health product under this Act and the repeal of the Medicines Act, the Minister may, by order published in the *Gazette*, prescribe the appropriate words that are to replace, in each of those provisions, the words as specified in the second column of that Schedule.

PART XVI

OTHER REPEALS, TRANSITIONAL PROVISIONS, SAVINGS AND CONSEQUENTIAL AMENDMENTS

Amendment of Health Sciences Authority Act

81. Section 11 of the Health Sciences Authority Act (Cap. 122C) is amended —

(*a*) by deleting paragraphs (*a*) and (*b*) of subsection (1) and substituting the following paragraphs:

"(*a*) to regulate the manufacture, import, export, sale, supply, advertisement and use of health products, tobacco products, radioactive materials and irradiating apparatuses in accordance with the applicable written laws;

(*b*) to conduct technological assessments of health products for the purpose of determining their quality, safety, efficacy and suitability for consumption and use in Singapore and to advise the Government thereon;"; and

(*b*) by deleting subsection (5) and substituting the following subsection:

"(5) In this section —

"health product" means any substance, preparation or device —

(*a*) that is represented for use by humans;

(*b*) that, whether because of its presentation or otherwise, is likely to be taken for use by humans; or

(*c*) that is included in a class of substance, preparation or device which is or is ordinarily intended for use by humans,

solely or principally for a therapeutic, preventive, palliative, diagnostic, cosmetic or other health-related purpose, such as —

(i) preventing, diagnosing, monitoring, treating, curing or alleviating any disease, disorder, ailment, injury, handicap or abnormal physical or mental state, or the symptoms thereof, in humans;

(ii) compensating for any injury or handicap in humans;

(iii) investigating, modifying or replacing any part of the human anatomy or any physiological process in humans;

(iv) testing the susceptibility of humans to any disease, disorder or ailment;

(v) influencing, controlling or preventing conception in humans;

(vi) testing for pregnancy in humans;

(vii) inducing anaesthesia in humans;

(viii) destroying or inhibiting micro-organisms that may be harmful to humans;

(ix) cleansing, fragrancing, deodorising, beautifying, preserving, improving, altering or restoring the complexion, skin, hair or teeth of humans; or

(x) otherwise promoting or preserving human health and well-being;

"health sciences" includes forensic medicine, forensic science, clinical pharmacology, pharmaceutical science, radiation science, transfusion medicine and any other applied science or specialised scientific field that relates to human health;

"tobacco product" means any cigarette, cigar or any other form of tobacco which may be consumed through smoking, chewing or otherwise.".

Amendment of Medicines (Advertisement and Sale) Act

82. The Medicines (Advertisement and Sale) Act (Cap. 177) is amended in the manner set out in the Fifth Schedule.

Repeal of Poisons Act and consequential amendments arising therefrom

83.—(1) The Poisons Act (Cap. 234) is repealed.

(2) Paragraph 1 of the Schedule to the Patents Act (Cap. 221) is amended —

(*a*) by deleting paragraph (ii) of the definition of "Chinese Proprietary Medicine" and substituting the following paragraph:

"(ii) any substance that is prescribed as an active ingredient under Part IX of the Health Products Act 2005; or"; and

(*b*) by deleting paragraph (*d*) of the definition of "traditional medicine" and substituting the following paragraph:

"(*d*) any substance that is prescribed as an active ingredient under Part IX of the Health Products Act 2005; or".

Repeal of Sale of Drugs Act and consequential amendment arising therefrom

84.—(1) The Sale of Drugs Act (Cap. 282) is repealed.

(2) Section 2(1) of the Weights and Measures Act (Cap. 349) is amended by deleting the definition of "drug" and substituting the following definition:

“ “drug” means any substance or mixture of substances used by man as a medicine whether internally or externally, and includes anaesthetics, but does not include such substances or mixtures of substances when sold otherwise than for medicinal purposes, and also includes face powders, dusting powders and toilet preparations whether or not advertised or described as a drug and for whatever purpose sold;”.

FIRST SCHEDULE

Sections 4 and 29(1)

CLASSIFICATIONS AND DESCRIPTIONS OF HEALTH PRODUCTS

First column	*Second column*	*Third column*
Classification	*Description*	*Exceptions and Limitations*

SECOND SCHEDULE

Section 73(2) and (4)

MATTERS FOR OR IN RESPECT OF WHICH REGULATIONS MAY BE MADE UNDER SECTION 73

1. The matters in respect of which regulations may be made under section 73 are as follows:

(*a*) for prescribing the requirements in accordance with which the manufacture, import, supply, storage, transport, presentation, advertisement, administration and use of health products are to be carried out;

(*b*) for prohibiting the manufacture, import, supply, possession, storage, transport, advertisement, administration and use of health products that are dangerous to human health;

(*c*) for prescribing the standards for health products in relation to their composition, quality, efficacy and safety for use;

(*d*) for prescribing the requirements and procedure for obtaining any licence under this Act;

(*e*) for prescribing the requirements in accordance with which the manufacture, import, supply, storage and transport of active ingredients are to be carried out;

(*f*) for prescribing the requirements and procedure for the registration of a health product;

(*g*) for prescribing the duties and obligations of a person to whom any licence or registration is granted under this Act, and the duties and obligation of such person upon the suspension, revocation or cancellation of such licence or registration;

(*h*) for prescribing the requirements for the presentation and advertisement of health products;

(*i*) for controlling and regulating the use of health products in clinical trials;

(*j*) for prescribing the procedure for the procurement, testing, examination or analysis of any sample under this Act;

(*k*) for providing for the conduct by the Authority or an enforcement officer of routine inspections of —

(i) premises that are being used for the manufacture, supply or storage of healthcare products or active ingredients; or

(ii) conveyances that are being used for the transport of healthcare products or active ingredients;

(*l*) for implementing any international agreement to which Singapore is a party that concerns the regulation of the manufacture, import, supply, possession, storage, transport, presentation, advertisement, administration and use of health products and active ingredients;

(*m*) for providing for the protection of any confidential information that relates to any health product and that is received by the Authority or any enforcement officer in the course of administering and enforcing this Act, and for prescribing the purposes for which such confidential information may be disclosed to any specified person;

(*n*) for prescribing the offences that may be compounded under section 66; and

(*o*) for prescribing any other matter that is necessarily to be prescribed for the administration and enforcement of this Act.

2. Regulations made for the purposes specified in paragraph 1(*a*) and (*e*) may —

(*a*) restrict the class of persons by whom and the circumstances under which any health product or active ingredient may be manufactured, imported, supplied, kept in possession, stored, transported or used;

(*b*) restrict the class of persons to whom and the circumstances under which any health product or active ingredient may be supplied;

(*c*) restrict the places at which, the manner in which and the persons by whom any health product or active ingredient may be stored;

(*d*) require records to be kept or submitted to the Authority in relation to the manufacture, import, supply, possession, storage, transport or use of any health product or active ingredient; and

(*e*) make provisions for the regulation of places at which health products are supplied by retail.

3. Regulations made for the purposes of paragraph 1(*d*) and (*e*) may —

(*a*) restrict the classes of persons who may apply for a licence or registration under this Act;

(*b*) prescribe the requirements which must be satisfied by any person before a licence or registration may be granted to him;

(*c*) prescribe the information, documents and samples that must be submitted by the applicant for any licence or registration; and

(*d*) prescribe the types of assessment and evaluation to be made of any health product before it may be registered.

THIRD SCHEDULE

Section 79(*g*)

NEW PART VIIIA OF ANIMALS AND BIRDS ACT

"PART VIIIA

REQUIREMENTS WITH REGARD TO VETERINARY HEALTH PRODUCTS

Interpretation of this Part

59A. In this Part, unless the context otherwise requires —

"active ingredient" means a substance or compound that —

(*a*) is usable in the manufacture of a veterinary health product as a pharmacologically active ingredient; and

(*b*) is prescribed to be an active ingredient to which this Part applies;

"packaging", in relation to a veterinary health product, means the container and other packaging material in which the veterinary health product is supplied, and includes any informational sheet or leaflet that accompanies the veterinary health product when it is being supplied;

"presentation", in relation to a veterinary health product, means the way in which the veterinary health product is presented for sale or supply, and includes matters relating to the name of the veterinary health product, the labelling and packaging of the veterinary health product and any other informational material (for example, product inserts) associated with the veterinary health product;

"sample", in relation to any veterinary health product, includes a sample of the packaging of the health product;

"veterinary biologic" means any virus, serum, toxin or any other analogous product of natural or synthetic origin, including any genetically modified organism, diagnostic, antitoxin, vaccine, live micro-organism, killed micro-organism or the antigenic or immunizing component of any micro-organism intended for use in the diagnosis, treatment, or prevention of diseases of animals and birds, or for purposes of research in animals or birds;

"veterinary health product" means any substance, preparation, device or veterinary biologic that is intended, represented or likely to be taken for use in animals or birds solely or principally for —

(*a*) a therapeutic, preventive, palliative, diagnostic or cosmetic purpose (including for preventing, diagnosing, monitoring, treating, curing

or alleviating any disease, disorder, ailment, injury, handicap in animals or birds);

(*b*) research relating to the prevention, diagnosis, monitoring, treatment, cure or alleviation of any disease, disorder, ailment, injury, handicap in animals or birds; and

(*c*) any other purpose related to the promotion of veterinary health,

and includes any active ingredient used in the manufacture of any such veterinary health product.

Regulation of dealings in veterinary health products

59B.—(1) The Minister may, after consultation with the Authority, make rules to regulate the manufacture, import, export, registration, sale, supply, advertisement, storage, presentation, transport, possession, evaluation, analysis, administration and use of veterinary health products.

(2) Without prejudice to the generality of subsection (1), rules made under this section may —

(*a*) require any person who manufactures, imports, exports, possesses, sells or supplies any veterinary health product to be licensed by the Authority and to comply with —

(i) the conditions attached to the licence issued to him by the Authority; and

(ii) such directions as the Authority may from time to time give to licensees;

(*b*) prescribe the requirements in accordance with which the manufacture, import, export, sale, supply, advertisement, storage, possession, transport, presentation, administration or use of veterinary health products is to be carried out, including requirements —

(i) restricting the persons by whom and the circumstances under which the manufacture, import, export, sale, supply, storage, possession, transport, administration or use of any veterinary health product may be carried out;

(ii) restricting the premises and facilities at which, and the manner in which the manufacture, sale, supply, storage, or use of any veterinary health products may be carried out;

(iii) restricting the persons to whom, the purposes for which and the manner in which, any veterinary health product may be sold or supplied; and

(iv) providing for the keeping of proper records in relation to any manufacture, import, export, possession, storage, transport, sale, supply or use of any veterinary health product;

(*c*) prohibit the manufacture, import, export, sale, supply, advertisement, possession, storage, administration or use of any veterinary health product unless the veterinary health product has been registered in accordance with the prescribed requirements;

(*d*) prescribe the standards and other requirements for veterinary health products in relation to their formulation, composition, design specification, quality, safety, efficacy, packaging and presentation;

(*e*) prescribe the requirements and procedure for obtaining any licence or for the registration of a veterinary health product under this Part, including —

(i) the requirements which must be satisfied by any person before a licence or registration may be granted to him;

(ii) the information, documents and samples that must be submitted by the applicant for any licence or registration; and

(iii) the examination, analysis, assessment and evaluation to be made of any veterinary health product before it may be registered;

(*f*) prescribe the duties and obligations of a person to whom any licence or registration has been granted under this Part, including —

(i) the duty to keep and produce to the Authority for inspection such records as may be prescribed or otherwise required by the Authority to be kept;

(ii) the duty to furnish to the Authority such information as the Authority may from time to time require concerning any veterinary health product;

(iii) the duty to verify the quality, safety and efficacy of any veterinary health product if required by the Authority;

(iv) the duty to notify the Authority of any changes in relation to any veterinary health product that has been registered under this Part;

(v) the duty to notify the Authority of the defects and adverse effect associated with, or recall of any veterinary health product; and

(vi) the duties and obligation of such person upon the suspension, revocation or cancellation of the licence or registration that has been granted to him;

(*g*) provide for the implementation of any international agreement to which Singapore is a party that concerns the regulation of the manufacture, import, export, possession, transport, sale, supply or use of any veterinary health product; and

(*h*) provide for the protection of any confidential information that relates to any veterinary health product and that is received by the Authority or any authorised officer in the course of administering and enforcing this

Part, and prescribe the purposes for which such confidential information may be disclosed to any specified person.

(3) Regulations made pursuant to subsection (2)(*g*) for implementing any international agreement to which Singapore is a party shall have effect notwithstanding any written law or rule of law to the contrary.

(4) The Minister may, in making any rules under this section, provide that any contravention of, or failure or neglect to comply with, any provision of such rules or any directive issued by the Director-General pursuant to such rules shall be an offence punishable with a fine not exceeding $20,000 or with imprisonment for a term not exceeding 12 months or with both.

Enforcement of this Part

59C.—(1) For the purpose of the administration and enforcement of this Part, the Director-General or an authorised officer may —

(*a*) at any time and without warrant enter, inspect and search any premises that are being used, or that the Director-General or authorised officer has reason to suspect are being used, for or in connection with any purpose that is in contravention of this Part;

(*b*) at any time and without warrant stop, board, inspect and search any conveyance that is being used, or that the Director-General or authorised officer has reason to suspect is being used, for or in connection with any purpose that is in contravention of this Part;

(*c*) in accordance with such procedure as may be prescribed and without payment, take for testing, examination or analysis a sample of any veterinary health product that is found pursuant to an inspection or a search under paragraph (*a*) or (*b*);

(*d*) seize —

(i) any veterinary health product, wherever found, if the Director-General or authorised officer knows or has reason to suspect that the health product or active ingredient is a non-compliant health product or active ingredient; or

(ii) any other substance or article which the Director-General or authorised officer has reasonable cause to believe to be a substance or an article in relation to which, or by means of which, an offence under this Act is being or has been committed;

(*e*) require, by notice in writing, any person to attend at such reasonable time and at such place as may be specified by the Director-General or authorised officer to answer any question or to provide a signed statement in writing concerning any suspected contravention of this Act;

(*f*) arrest, without warrant, any person whom the Director-General or authorised officer has reason to believe has committed any offence under this Part if —

(i) the name and address of that person are unknown;

(ii) the person refuses to furnish his name or address;

(iii) the person furnishes an address out of Singapore;

(iv) the Director-General or authorised officer has reasonable grounds for believing that the person has furnished a false name or address; or

(v) the Director-General or authorised officer has reasonable grounds for believing that the person is likely to abscond;

(*g*) require any person —

(i) to furnish any information within his knowledge; or

(ii) to produce for inspection any document or record within his possession,

that the Director-General or authorised officer believes on reasonable grounds to be connected with any suspected contravention of this Act or to be otherwise relevant to the administration or enforcement of this Act;

(*h*) retain the original copy of any document or record that the Director-General or authorised officer believes on reasonable grounds to be connected with any suspected contravention of this Act or to be otherwise relevant to the administration or enforcement of this Act, or make or cause to be made, without payment, copies of or extracts from such document or record; and

(*i*) require, by notice in writing, any person having in his possession any veterinary health product that is intended for sale or supply to submit, at his own expense, a sample of such veterinary health product to an authorised examiner for analysis.

(2) In exercising his power under subsection (1)(*a*) or (*b*), the Director-General or an authorised officer may —

(*a*) require the owner or occupier of any premises or conveyance being inspected to provide all reasonable assistance to the Director-General or authorised officer (as the case may be) for the purpose of the inspection; and

(*b*) if the circumstances so warrant, with such assistance as he thinks necessary, break open any door, window, lock, fastener, hold, compartment, box, container, receptacle or any other thing,

and any person who fails to comply with any requirement of the Director-General or an authorised officer under paragraph (*a*) shall be guilty of an offence and shall

be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(3) The Director-General may, by notice in writing, require any person who has supplied any veterinary health product to recall, within such period as may be specified in the notice, all such veterinary health product if the Director-General has reason to believe that such veterinary health product does not comply with the requirements of this Part.

(4) The Director-General may, by notice in writing, require any person who manufactures, imports, exports, sells or supplies any veterinary health product to cease (whether immediately or within such time as the Director-General may specify) the manufacture, import, export, sale or supply of such veterinary health product if —

(*a*) the Director-General has reason to believe that such veterinary health product does not comply with the requirements of this Part; or

(*b*) a sample of the veterinary health product has been taken or obtained under subsection (1)(*c*) or (*i*) and sent for analysis and pending the result of the analysis, the Director-General is of the opinion that it is necessary to prevent any more of such veterinary health product from being manufactured, imported, exported, sold or supplied.

(5) Where any person is in possession of any veterinary health product that does not comply with the requirements of this Part, the Director-General may, if he thinks necessary for the purpose of preventing such veterinary health product from being exported, sold or supplied by that person, by notice in writing require that person to destroy or dispose of the veterinary health product in such manner as may be specified in the notice.

(6) Where any item is seized under subsection (1)(*d*) —

(*a*) the Director-General or the authorised officer making such seizure shall immediately give notice in writing of the seizure to the person from whom the item is seized, if his name and address are known;

(*b*) any person claiming the item seized may within 48 hours after the seizure complain thereof to a Magistrate, and the complaint may be heard and determined by the Magistrate who may —

(i) confirm the seizure wholly or in part;

(ii) disallow the seizure wholly or in part;

(iii) order that the item seized be restored to its owner, subject to such condition which the Magistrate may think fit to impose to ensure that the item is preserved for any purpose for which it may subsequently be required; or

(iv) order payment to be made to the owner of the item seized of such amount as the Magistrate considers will compensate him for any loss or depreciation resulting from the seizure;

(*c*) in the absence of any claim under paragraph (*b*) or pending the determination of any such claim, the item may be kept or stored in the premises or conveyance where it was seized or may, at the direction of the Director-General or authorised officer, be removed to any other place to be kept or stored thereat;

(*d*) the Director-General or authorised officer may —

(i) mark, seal or label the item in such manner as he thinks fit for the purpose of indicating that the item is under detention; and

(ii) lock or seal the premises or conveyance in which the item is being detained; and

(*e*) any person who, without the authority of the Director-General or an authorised officer —

(i) interferes, tampers with, removes, distributes, sells or otherwise disposes of the item;

(ii) alters, counterfeits, defaces, destroys, erases or removes any mark, seal or label placed by the Director-General or authorised officer on the item under paragraph (*d*)(i); or

(iii) opens, breaks or otherwise tampers with the lock or seal placed by the Director-General or authorised officer on any premises or conveyance or part thereof under paragraph (*d*)(ii),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(7) No person arrested under subsection (1)(*f*) shall be detained longer than is necessary for bringing him before a court unless the order of a court for his detention is obtained.

(8) For the purposes of subsection (1)(*g*), where any document or record required by the Director-General or an authorised officer is kept in electronic form, then —

(*a*) the power of the Director-General or authorised officer to require any such documents or records to be produced for inspection includes power to require a copy of the documents or records to be made available for inspection in legible form (and subsection (1)(*h*) shall accordingly apply in relation to any copy so made available); and

(*b*) the power of the Director-General or authorised officer to inspect such document or record includes the power to require any person on the premises in question to give the Director-General or authorised officer such assistance as the Director-General or authorised officer may reasonably require to enable him —

(i) to inspect and make copies of the document or record in legible form or to make records of the information contained therein; or

(ii) to inspect and check the operation of any computer, and any associated apparatus or material, that is or has been in use in connection with the keeping of the document or record.

(9) Any copy of or extract from any document made under subsection (1)(*h*) and certified as such by the Director-General or authorised officer shall be admissible as evidence in any proceedings under this Part.

(10) Any person who, when required by the Director-General or an authorised officer under subsection (1)(*g*) to furnish any information or produce any document or record, refuses or fails, without reasonable excuse, to furnish the information or to produce the document or record within the time allowed by the Director-General or authorised officer shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(11) Any person who, when required by the Director-General or an authorised officer —

(*a*) under subsection (1)(*e*) to answer any question or to provide any signed statement in writing; or

(*b*) under subsection (1)(*g*) to furnish any information or produce any document or record,

in compliance or purported compliance with such requirement, furnishes the Director-General or authorised officer with any information, document or record which he knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(12) Any person who fails, without reasonable excuse, to comply with any notice in writing given to him —

(*a*) by the Director-General or authorised officer under subsection (1)(*e*) or (*i*); or

(*b*) by the Director-General under subsection (3), (4) or (5),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

Presumptions for enforcement of this Part

59D.—(1) Where any veterinary health product is supplied in a package, any person who appears from any statement thereon or attached thereto to have imported or manufactured that veterinary health product shall, until the contrary is proved, be presumed to have so imported or manufactured the veterinary health product.

(2) Where any veterinary health product is advertised, the person whose name or particulars appear in the advertisement shall, until the contrary is proved, be presumed to be the person who has advertised the veterinary health product.

(3) Any person who manufactures, imports or supplies any veterinary health product shall be presumed, until the contrary is proved, to have manufactured, imported or supplied the health product for use as a veterinary health product.

(4) Any veterinary health product that is found —

(*a*) on any premises that are used for the manufacture, storage or supply of veterinary health products; or

(*b*) in any conveyance that is used for the transportation of veterinary health products; or

shall be presumed, until the contrary is proved, to be intended for use as a veterinary health product.

(5) Any quantity of a veterinary health product found in or on any premises or conveyance at the time when a sample thereof is taken pursuant to the provisions of this Part shall, unless the contrary is proved, be deemed to possess the same properties as such sample.

Presumption of person's intention to sell or supply veterinary health product found in his possession

59E. Where any person is found to be keeping or to be in possession of any veterinary health product in circumstances in which it would be reasonable to suspect that he intends to sell or supply the veterinary health product, he shall be presumed, until the contrary is proved, to have the veterinary health product in his possession for the purpose of sale or supply.".

FOURTH SCHEDULE

Section 80(2) and (3)

ACTS TO BE AMENDED UPON CLASSIFICATION OF MEDICINAL PRODUCTS AS HEALTH PRODUCTS

	First column *Act and provision therein to be amended*	*Second column* *Words to be replaced with appropriate prescribed words*
1.	Control of Manufacture Act (Cap. 57, 2001 Ed.) First Schedule, item 10	"a medicinal product within the meaning of the Medicines Act (Cap. 176)".
2.	Patents Act (Cap. 221, 2002 Ed.) Section 2(1)	(*a*) "marketing approval" , in relation to a pharmaceutical product, means a product licence under section 5 of the Medicines Act (Cap. 176);"; and (*b*) "medicinal product" has the same meaning as in the Medicines Act;".
3.	Smoking (Control of Advertisements and Sale of Tobacco Act (Cap. 309, 2003 Ed.) Section 2 (Definition of "tobacco product")	"any medicinal product registered under the Medicines Act (Cap. 176)".

FIFTH SCHEDULE

Section 82

AMENDMENTS TO MEDICINES (ADVERTISEMENT AND SALE) ACT

	Provision	*Amendment*
1.	Long title	Delete the words "and to regulate the sale of substances recommended as a medicine".
2.	Section 1	Delete the words "Medicines (Advertisement and Sale) Act" and substitute the words "Medical Services (Advertisements) Act".
3.	Section 2	Delete the definitions of "Poisons List", "proprietary designation", "public hospital", "substance" and "substance recommended as a medicine".
4.	Section 3	Repeal.
5.	Section 5	(*a*) Delete the words ", or to any article or articles of any description,"; and (*b*) Delete the words ", or to lead to the use of that article or articles of that description,".
6.	Section 6	(*a*) Delete "3," in subsections (1) and (3) (1st line). (*b*) Delete subsection (2). (*c*) Delete the words "and holders of licences to sell poisons set out in the Schedule to the Poisons Act" in subsection (3)(*b*)(iv). (*d*) Delete the marginal reference "Cap. 234" to subsection (3)(*b*)(iv). (*e*) Delete "3," in the marginal note.
7.	Section 7	Repeal.
8.	The Schedule	Repeal.

EXPLANATORY STATEMENT

This Bill seeks —

(*a*) to regulate the manufacture, import, supply, presentation and advertisement of health products and active ingredients used in the manufacture thereof;

(*b*) to provide for the transition of the regulation of medicinal products from the Medicines Act (Cap. 176) to the Bill and thereafter to repeal the Medicines Act;

(*c*) to amend and rename the Medicines (Advertisement and Sale) Act (Cap. 177);

(*d*) to repeal the Poisons Act (Cap. 234) and the Sale of Drugs Act (Cap. 282); and

(*e*) to make consequential amendments to certain other written laws.

PART I

PRELIMINARY

Part I deals with preliminary matters.

Clause 1 relates to the short title and commencement.

Clause 2 defines certain terms used in the Bill.

Clause 3 sets out the purposes of the Bill.

Clause 4 clarifies that the Bill applies only to health products classified and described in the First Schedule. The clause also empowers the Minister for Health (the Minister) to specify in the First Schedule the extent to which the provisions of the Bill will apply to any health product listed in that Schedule.

Clause 5 provides that the provisions of the Bill will not apply in relation to the supply or use of registered health products for veterinary purposes except to the extent provided for by Part XIV (Part XIV empowers the Minister for National Development to make regulations to regulate the supply and use of registered health products for veterinary purposes. Such regulations will be administered and enforced by the Agri-Food and Veterinary Authority.).

PART II

ADMINISTRATION

Part II contains provisions concerning the administration of the Bill.

Clause 6 provides that the Health Sciences Authority (the Authority) will be responsible for the administration and enforcement of the Bill (with the exception of Part XIV).

Clause 7 empowers the Chief Executive to appoint enforcement officers for the purpose of enforcing the Bill.

Clause 8 empowers the Chief Executive to designate suitably qualified persons as analysts to carry out any test, evaluation or analysis as may be necessary for the purpose of the administration and enforcement of the Bill.

Clause 9 deems all enforcement officers and analysts to be public servants within the meaning of the Penal Code (Cap. 224).

Clause 10 empowers the Authority to establish Advisory Committees for the purpose of advising the Authority on matters arising out of the administration and enforcement of the Bill.

Clause 11 empowers the Minister to establish Appeal Advisory Committees for the purpose of assisting him in his determination of any appeal brought to him under the Bill and advising him on any matter arising out of any such appeal.

PART III

MANUFACTURE AND IMPORT OF HEALTH PRODUCTS

Part III contains provisions regulating the manufacture and import of health products.

Clause 12 prohibits any person from manufacturing any health product unless he holds a valid manufacturer's licence issued by the Authority and the manufacture of the health product complies with the other requirements of the clause.

Clause 13 prohibits any person from importing any health product unless he holds a valid importer's licence issued by the Authority and the import of the health product complies with the other requirements of the clause. The clause also prohibits any person from importing adulterated, counterfeit or unwholesome health products or health products that have been tampered with.

PART IV

SUPPLY OF HEALTH PRODUCTS

Part IV contains provisions regulating the supply of health products.

Clause 14 prohibits any person from supplying any health product by wholesale unless he holds a valid wholesaler's licence issued by the Authority and the wholesale supply of the health product complies with the other requirements of the clause.

Clause 15 prohibits any person from supplying any health product unless either the health product is registered under the Bill or, if it is not so registered, the supply is approved by the Authority for certain specified purposes.

Clause 16 prohibits any person from supplying adulterated, counterfeit or unwholesome health products or health products that have been tampered with.

Clause 17 requires the supply of health products to be carried out in accordance with such requirements as may be prescribed.

Clause 18 prohibits any person from supplying any health product unless the presentation of the health product complies with such requirements as may be prescribed.

PART V

ADVERTISEMENT OF HEALTH PRODUCTS

Part V contains provisions regulating the advertisement of health products.

Clause 19 prohibits the advertisement of unregistered health products.

Clause 20 prohibits false or misleading advertisements of health products.

Clause 21 requires advertisements of health products to comply with such requirements as may be prescribed.

Clause 22 provides a defence for persons in the publishing trade against the offences under clauses 19, 20 and 21.

Clause 23 empowers the Authority to require any person who has advertised any health product in contravention of clause 19, 20 or 21 to take certain corrective measures to put right any misrepresentation, misinformation or misimpression that may have been caused by that advertisement.

PART VI

LICENCES

Part VI contains provisions relating to the application, issue, renewal, suspension and revocation of licences.

Clause 24 sets out the procedure for the application, issue and renewal of licences under the Bill.

Clause 25 allows for a licensee to apply to the Authority for a variation of the conditions of his licence.

Clause 26 requires the Authority to keep a register of licensees.

Clause 27 provides for when and how the Authority may suspend or revoke any licence issued by it under the Bill.

Clause 28 provides for an avenue of appeal to the Minister against certain decisions made by the Authority under the Part.

PART VII

REGISTRATION OF HEALTH PRODUCTS

Part VII contains provisions concerning the registration of health products.

Clause 29 provides that the Authority must register health products in accordance with the classifications set out in the First Schedule. The clause also empowers the Authority to subdivide each classification of health products into such categories as it thinks fit and to register any health product under the category that it thinks appropriate.

Clause 30 sets out the procedure for the registration of health products.

Clause 31 provides that the registration of a health product will remain in force for so long as the registrant continues to pay the prescribed fee, and for so long as the registration is not suspended or revoked.

Clause 32 empowers the Authority to attach conditions to the registration of a health product.

Clause 33 provides for the evaluation of health products before registration.

Clause 34 requires the Authority to keep a Register of Health Products listing all health products registered under the Bill.

Clause 35 allows for the registrant of a health product to apply for a change in the classification or categorisation of the health product.

Clause 36 empowers the Authority of its own volition to change the classification or categorisation of a health product where it thinks necessary.

Clause 37 requires the registrant of a health product to notify the Authority of certain changes that have been made to the health product since its registration.

Clause 38 provides for when and how the Authority may suspend or cancel the registration of a health product.

Clause 39 provides for an avenue of appeal to the Minister against certain decisions made by the Authority under the Part.

PART VIII

DUTIES OF MANUFACTURERS, IMPORTERS, ETC., OF HEALTH PRODUCTS

Part VIII contains provisions imposing various duties on manufacturers, importers, suppliers and registrants of health products.

Clause 40 provides that the duties imposed by the Part on manufacturers, importers, suppliers and registrants of health products are in addition to those duties imposed on them under Part III, IV or VII.

Clause 41 requires manufacturers, importers, suppliers and registrants of health products to keep certain records.

Clause 42 requires manufacturers, importers, suppliers and registrants of health products to furnish the Authority with certain information or documents when so required by the Authority.

Clause 43 requires the manufacturer, importer, supplier or registrant of a health product to inform the Authority if he becomes aware of any defect in the health product or any adverse effect that has arisen or can arise from the use of the health product. The clause also empowers the Authority to take certain remedial actions to deal with such defect or adverse effect.

Clause 44 requires the manufacturer, importer, supplier or registrant of a health product to verify the quality, safety or efficacy of the health product when so required by the Authority in certain given circumstances.

Clause 45 requires the manufacturer, importer, supplier or registrant of a health product to inform the Authority should he recall the health product.

Clause 46 empowers the Minister, after consultation with the Authority, to make regulations to provide for additional duties to be imposed on manufacturers, importers, suppliers and registrants of health products.

PART IX

REGULATION OF DEALINGS IN ACTIVE INGREDIENTS

Part IX contains provisions for the regulation of dealings in active ingredients.

Clause 47 defines what is meant by an "active ingredient" for the purposes of the Part.

Clause 48 empowers the Minister, after consultation with the Authority, to make regulations to control and regulate the manufacture, import, supply, transport, possession and storage of active ingredients.

PART X

ENFORCEMENT

Part X contains provisions relating to the enforcement of the Bill.

Clause 49 defines what is meant by a "non-compliant health product" or a "non-compliant active ingredient" for the purposes of the Part.

Clause 50 sets out the powers that enforcement officers may exercise when administering and enforcing the Bill.

Clause 51 makes it an offence for any person to alter, suppress, conceal or destroy any document which he is or is liable to be required under the Bill to produce to an enforcement officer.

Clause 52 makes it an offence for any person to obstruct, hinder or impede any enforcement officer or any other person acting under the direction of the Authority or its Chief Executive in the performance or execution of his duty under the Bill.

PART XI

PRESUMPTIONS AND OTHER EVIDENTIARY PROVISIONS FOR PURPOSES OF ENFORCEMENT OF ACT

Part XI contains provisions which set out certain presumptions and evidentiary matters for the purposes of the enforcement of the Bill. All the presumptions under the Part are rebuttable.

Clause 53 presumes a person to be an importer or a manufacturer of a health product or an active ingredient if he is stated on the package of the health product or active ingredient to be the importer or manufacturer thereof.

Clause 54 presumes a person to be the advertiser of a health product if his name appears in the advertisement.

Clause 55 presumes a person who has manufactured, imported or supplied a health product to have so manufactured, imported or supplied the health product for use by humans. The clause presumes that health products found in certain circumstances are intended for use by humans.

Clause 56 presumes that any health product or active ingredient from which a sample has been taken pursuant to the provisions of the Bill will have the same properties as the sample.

Clause 57 presumes a person to be keeping or possessing any health product for the purpose of supply if he is found to be keeping or to be in possession of the health product in circumstances in which it would be reasonable to suspect that he intends to supply the health product.

Clause 58 provides for the admissibility in evidence of the certificate of an analyst.

PART XII

OFFENCES AND PROSECUTION

Part XII contains provisions relating to the prosecution of offences under the Bill.

Clause 59 confers jurisdiction on a District Court to try any offence under the Bill and to impose the full penalty or punishment in respect of the offence.

Clause 60 makes certain officers of a body corporate or an unincorporated body liable for offences committed by the body corporate or unincorporated body.

Clause 61 provides for enhanced penalties to be imposed on corporations which commit offences under the Bill.

Clause 62 makes a person liable, in certain circumstances, for the offences under the Bill which are committed by his agent or servant.

Clause 63 provides for the forfeiture of items seized pursuant to the enforcement provisions of the Bill.

Clause 64 empowers the court, when convicting a person of an offence under the Bill, to order him to pay the costs and expenses relating to the purchase and analysis of any sample of the health product or active ingredient in respect of which the conviction is obtained, as well as any other reasonable expenses incurred by the prosecution.

Clause 65 protects the prosecutor or witness in any prosecution of an offence under the Bill from being compelled to disclose certain information.

Clause 66 provides for the composition of offences under the Bill.

PART XIII

MISCELLANEOUS

Part XIII contains certain miscellaneous provisions.

Clause 67 provides for the protection of certain confidential information obtained by any person who is or has been involved in the administration and enforcement of the Bill.

Clause 68 provides for the service of documents under the Bill.

Clause 69 relates to the form and authentication of notices, orders and other documents under the Bill.

Clause 70 provides that certain inaccuracies in documents issued under the Bill will not invalidate proceedings under the Bill.

Clause 71 empowers the Authority to exempt any person or class of persons or any health product or class of health products from all or any of the provisions of the Bill, subject to any general or special direction of the Minister.

Clause 72 empowers the Authority, with the approval of the Minister, to make regulations to prescribe the fees that are payable under and for the purposes of the Bill and the time at which and the manner in which any such fee is to be paid. The clause also provides for all fees collected under the Bill to be paid into the fund of the Authority.

Clause 73 empowers the Minister, after consultation with the Authority, to make regulations for carrying out the purposes and provisions of the Bill. Some of the matters in respect of which regulations may be made under the clause are listed in the Second Schedule.

PART XIV

REGULATION OF SUPPLY AND USE OF REGISTERED HEALTH PRODUCTS AND ACTIVE INGREDIENTS FOR VETERINARY PURPOSES

Part XIV, which will be administered by the Minister for National Development and the Agri-Food and Veterinary Authority, contains provisions for the regulation of the supply and use for veterinary purposes of health products that have been registered by the Health Sciences Authority under the Bill.

Clause 74 empowers the Minister for National Development, after consultation with the Agri-Food and Veterinary Authority, to make regulations in relation to the supply and use of registered health products or active ingredients for veterinary purposes.

Clause 75 provides that an officer of the Agri-Food and Veterinary Authority administering and enforcing any regulations made under clause 74 will have the same

powers as are conferred on an enforcement officer of the Health Sciences Authority by clause 50.

Clause 76 provides that the provisions of the following Parts:

(*a*) Parts X (Enforcement);

(*b*) Part XI (Presumptions and other evidentiary provisions for purposes of enforcement of Act);

(*c*) Part XII (Provisions relating to offences and prosecution); and

(*d*) Part XIII (Miscellaneous),

will, where relevant, apply with the modifications as set out in the clause to the administration and enforcement of any regulations made under clause 74.

PART XV

PROVISIONS FOR TRANSFERRING REGULATION OF MEDICINAL PRODUCTS FROM MEDICINES ACT TO THIS ACT

Part XV contains provisions to effect the transfer of the regulation of medicinal products from the Medicines Act (Cap. 176) to the Bill. Medicinal products will be classified as a type of health product in the First Schedule and will be regulated in accordance with the provisions of the Bill. Once every type of medicinal product currently being regulated under the Medicines Act has been classified as a type of health product and is being regulated under the Bill, the Medicines Act will be repealed.

Clause 77 amends the Medicines Act by inserting a new section 77.

The new section 77 provides that the Medicines Act will no longer apply to any medicinal product that has been classified as a health product under the Bill. This is to avoid duplicity of regulation.

Clause 78 provides for the repeal of the Medicines Act. The clause will be brought into operation only after all the medicinal products currently being regulated under that Act have been classified as health products and are being regulated under the Bill.

Clause 79 makes certain consequential amendments to the Animals and Birds Act (Cap. 7) arising from the repeal of the Medicines Act.

The Medicines Act is currently being jointly administered by the Ministry of Health and the Health Sciences Authority on the one part, and the Ministry of National Development and the Agri-Food and Veterinary Authority on the other part.

The Ministry of National Development and the Agri-Food and Veterinary Authority regulates veterinary medicines under the Medicines Act. As such, upon the repeal of the Medicines Act, the necessary provisions for the regulation of veterinary medicines will be incorporated in the Animals and Birds Act. These consequential amendments are set out in the Third Schedule. They empower the Minister for National Development, after consultation with the Agri-Food and Veterinary Authority, to make

rules to regulate the manufacture, import, export, sale, supply, advertisement, storage, presentation, transport, possession, evaluation, analysis, administration and use of veterinary health products.

Clause 80 makes certain consequential amendments to the Pharmacists Registration Act (Cap. 230) and to the Acts listed in the Fourth Schedule, arising from the repeal of the Medicines Act (Cap. 176).

PART XVI

OTHER REPEALS, TRANSITIONAL PROVISIONS, SAVINGS AND CONSEQUENTIAL AMENDMENTS

Part XVI contains miscellaneous repealing, transitional, saving and consequential provisions.

Clause 81 amends section 11 of the Health Sciences Authority Act (Cap. 122C) to bring the section in line with the provisions of the Bill.

Clause 82 amends the Medicines (Advertisement and Sale) Act (Cap. 177) to remove certain provisions that are no longer necessary upon the enactment of the Bill. These amendments are listed in the Fifth Schedule.

The clause also renames that Act as the "Medical Services (Advertisements) Act", which will more suitably reflect its remaining provisions.

Clause 83 repeal the Poisons Act (Cap. 234) since that Act will no longer be necessary upon the enactment of the Bill, and makes certain consequential amendments to the Patents Act (Cap. 221) arising from the repeal.

Clause 84 repeals the Sale of Drugs Act (Cap. 282) since that Act will no longer be necessary upon the enactment of the Bill, and makes certain consequential amendments to the Weights and Measures Act (Cap. 349) arising from the repeal.

The First Schedule, which is related to clauses 4 and 29, sets out the classifications and descriptions of health products for the purposes of the Bill.

The Second Schedule, which is related to clause 73, sets out certain matters in respect of which regulations may be made under that clause.

The Third Schedule, which is related to clause 79, sets out the provisions of the new Part VIIIA which will be incorporated into the Animals and Birds Act (Cap. 7) in consequence of the repeal of the Medicines Act.

The Fourth Schedule, which is related to clause 80, sets out the consequential amendments that will be made to certain Acts upon the repeal of the Medicines Act.

The Fifth Schedule, which is related to clause 82, sets out the consequential amendments that will be made to the Medicines (Advertisement and Sale) Act (Cap. 177) arising from the enactment of the Bill.

EXPENDITURE OF PUBLIC MONEYS

This Bill will not involve the Government in any extra financial expenditure.

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