Cosmetics, Devices and Drugs Act, 1980

Act No. 27 of 1980

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Preliminaries

(Certified on 17th July, 1980)
L D- O 61/78

An Act to regulate and control the manufacture, importation, sale and distribution of cosmetics, devices and drugs, to establish a Cosmetics, Devices and Drugs Technical Advisory Committee and to provide for matters connected therewith or incidental thereto.

Be it enacted by the Parliament of the Democratic Socialist Republic of Sri Lanka as follows:-

Short title and date of operation

1. This act may be cited as the Cosmetics, Devices and Drugs Act, No. 27 of 1980, and shall come into operation on such date as the Minister may, by Order published in the Gazette, appoint.

Prohibition in Respect of Cosmetics, Devices and Drugs

(Licensing of persons and Premises for manufacturing & c. cosmetics.

(1) No person shall manufacture or import any cosmetic without a license issued by the Cosmetics, Devices and Drugs Authority.

No person shall manufacture, prepare, store or sell any cosmetic in any premises unless such premises has been licensed by the Cosmetics, Devices and Drugs Authority.

Prohibition of Manufacture, importation sale and distribution of cosmetics.

3.(1) No person shall manufacture, prepare, preserve, package or store for sale any cosmetic under insanitary conditions.

(2) No person shall import, distribute offer for sale or sell any cosmetic that-

(a) was manufactured , prepared, preserved, packaged or stored for sale under insanitary conditions:

(b) consists in whole or in part if any filthy or decomposed substance or any foreign matter; or

(c) has in or upon it any substance that may cause injury to the health of the user when the cosmetic is used-

(i) according to the directions on the label accompanying the cosmetic; or

(ii) for such purposes and by such methods of use as are customary or usual in the use of that cosmetic.

Where standard is prescribed for cosmetic.

4. Where a standard is prescribed for any cosmetic, no person shall label, package, sell, offer for sale or distribute any cosmetic which does not conform to that standard in such a manner as is likely to be mistaken for the cosmetic for which the standard has been prescribed.

Prohibition on manufacture, importation, sale and distribution & c. of devices

5. No person shall manufacture, import, sell, offer for sale or distribute any device that may cause any injury to the health of the user when that device is used-

(a) under conditions that are customary or usual in the use of that device; or

(b) according to the direction on the label accompanying that device.

Licensing of person for manufacture & c. of devices

6. No person shall manufacture, import sell, offer for sale or distribute any device without a license issued by the Cosmetics, Devices and Drugs Authority.

Labeling packaging and Advertising devices.

7.(1) No person shall label, package, treat, process, sell or distribute or offer for sale or advertise any device in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its composition, merit or safety.

(2) A device that is not labelled or packaged as required by the regulations made under this Act or labelled or packaged contrary to those regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Where standard is prescribed for devices.

8. Where a standard is prescribed for any device, no person shall label, package, sell, Offer for sale or distribute or advertise any advice which does not conform to that Standard in such a manner as is likely to be mistaken for the device for which the Standard has been prescribed.

Licensing of Persons and premises for manufacturing & c. drugs.

9. (1) No person shall manufacture, import, sell or distribute or offer for sale any drug without a license issued by the Cosmetics, Devices and Drugs Authority.

(2) No person shall manufacture, prepare store or sell any drugs in any premises unless such premises has been licensed by the cosmetics, devices and drugs Authority.

Probation on manufacture, sale and distribution of drugs.

10(1) No person shall manufacture, prepare, preserve, package or store for sale any drug under insanitary conditions or any drug which is adulterated.

(2) No person shall import, sell of distribute or offer for sale any drug that-

(a) was manufactured, prepared, preserved, packaged or stored for sale under insanitary conditions : or

(b) is adulterated.

Labeling, packaging and advertising Drugs.

11. (1) No person shall label, package, treat, process, sell or distribute or offer for sale or advertise any drug in a manner that is false, misleading,

deceptive or likely to create an erroneous impression regarding its character, value, potency, quality, composition, merit or safety.

(2) A drug that is not labelled or packaged as required by the regulations made under this Act or is labelled or packaged contrary to such regulations shall be deemed to be labelled or packaged contrary to subsection (1).

Labeling & c., in conformity with the standard.

12 (1) Where a standard is prescribed for any drug, no person shall label, package, sell, offer for sale, distribute or advertise any drug which does not conform to such standard in such a manner as is likely to be mistaken for the drug for which a Standard has been prescribed.

(2) Where a standard has not been prescribed for any drug, but a standard for that drug is contained in any publication set out in Schedule 'A' , no person shall label, package, sell, offer for sale, distribute or advertise any drug which does not conform to the standard contained in that publication.

(3) Where a standard has not been prescribed for any drug, or a standard for that drug is not contained in any publication set out in schedule 'A' no person shall sell, offer for sale or distribute such drug-

(a) unless it is in conformity with the standard set out in the out in the label accompanying the drug; or

(b) in such a manner as is likely to be mistaken for a drug for which a standard has been prescribed or for which a standard is contained in any publication set out in Schedule 'A'.

Sale of certain drugs prohibited Unless Premises and Process of Manufacture Have been Approved.

13. No person shall sell, offer for sale or distribute any drug, described in Schedule 'B' or Schedule 'C' unless the premises in which the drug was manufactured and the process And the process and conditions of manufacture of that drug have been approved in the Prescribed from and manner as being suitable to ensure that the drug will be safe for use.

Sale of certain drugs Prohibited unless the batch from which the drug is taken is approved as reliable.

14. No person shall sell, offer for sale or distribute any drug described in Schedule 'D' unless the batch from which that drug was taken has been approved

in the prescribed form and manner as reliable for use.

Distribution of samples prohibited.

15. No person shall distribute or cause to be distributed any drug as a sample:

Provided that the preceding provisions of this section shall not apply to the distribution under prescribed conditions of any sample of a drug to a medical practitioner, dentist, or veterinary surgeon.

Total prohibition on sale of certain drugs.

16. No person shall sell, offer for sale or distribute any drug described in Schedule 'E'.

Advertisement importation, sale and distribution of cosmetics, device and drug as treatment for certain diseases prohibited.

17. (1) No person shall advertise any cosmetic, device or drug to the public as a treatment, prevention or cure for any of the diseases, disorders, or abnormal physical states set out in Schedule 'F'.

(2) No person shall import, sell, offer for sale, or distribute any cosmetic , device or drug-

(a) that is represented by a label; or

(b) that is advertised to the public,

as a treatment, prevention or cure for any of the diseases, disorders or abnormal physical states set out in Schedule 'F'.

AdministrationCosmetic Devices and Drugs Technical Advisory Committee

18.(1) There shall be a Committee which shall be called the cosmetics, Devices and Drugs Technical Advisory Committee (hereinafter referred to as the "Committee") consisting of -

(a) the Director of Health Services who shall be the Chairman of the Committee;

(b) the Assistant Director of Health Services in charge of cosmetics , Device

and Drugs control Administration who shall be the Secretary of the committee;

(c) the Professor of pharmacology of the University of Colombo;

(d) the pharmacologist of the Medical Research Institute;

(e) the Chairman of the State Pharmaceuticals Corporation;

(f) the Superintendent of the State Medical Stores;

(g) the Government Analyst or any officer nominated by him;

(h) the officer in charge of the Drugs Quality Control Laboratory;

(i) a consultant physician nominated by the Minister;

(j) a consultant surgeon nominated by the Minister;

(k) a representative of the Pharmaceutical Manufacturers' Association nominated by that Association;

(1) a representative of the Bureau of Ceylon Standards, nominated by the Minister in charge of the subject of Industries;

(m) a representative of the Pharmaceutical Society of Sri Lanka nominated by that Society;

(n) a representative of the Sri Lanka Medical Association nominated by that Association; and

(o) a representative of the Independent Medical Practitioners' Association nominated by that Association.

(2) Every member of the Committee nominated under paragraphs (i), (j), (k), (1), (m), (n) or (o) of subsection(1) shall, unless he earlier vacates office by resignation, death or removal, hold office for a period of three years from the data of nomination and shall be eligible for renomination.

(3) Every member of the Committee, other than the members referred to in subsection (2), shall cease to be a member of the Committee on his ceasing to hold office which qualified him to be a member of the Committee.

(4) The Committee may discharge its functions notwithstanding any vacancy among its members.

(5) Five members of the Committee shall constitute a quorum for any meeting of the Committee.

(6) Subject to the provisions of this Act, the Committee may regulate its own procedure in regard to its meetings and the transaction of business at the meetings.

Duties of the committee

19. (1) It shall be the duty of the Committee to advise the Minister on matters arising out of the administration of this Act and to carry out other functions assigned to it under this Act.

(2) The Committee may appoint such sub-committees as it deems fit to exercise such powers or perform such duties as may, subject to such conditions, if any, as the Committee may impose, be delegated to them by the Committee, and may appoint to those sub-committees persons who are not members of the Committee.

Cosmetics Devices and drugs Authority

20. (1) For the purposes of this Act, the Director of Health Services shall be the Cosmetics, Devices and Drugs Authority (hereinafter referred to as the "Authority").

′(2) Every drug shall be registered with the Authority.

(3) The Director of Health Services may with the approval of the Minister delegate all or any of his powers
as the Authority under this Act to any person by name or office.

Authorised Officers.

21. (1) The Minister may approve any Superintendent of Health Services, any Medical Officer of Health, any Public Health Inspector, any Food and Drugs Inspector and any Drugs Inspector to be an Authorized Officer for the purposes of this Act.

(2) Every Authorized Officer shall exercise the powers of a police officer in terms of the Code of Criminal Procedure Act, No. 15 of 1979, for the purpose of discharging his functions under this Act.

Powers of Authorised Officers.

22.(1) An Authorized Officer may, for the performance of his duties and the

exercise of his powers-

(a) at any reasonable time enter any place where he believes any article is manufactured, prepared,
packaged, preserved or stored and examine any such article and take samples thereof, and also
examine anything that he believes is used for the manufacture, preparation, preservation, packaging
or storing of such article;

(b) open and examine any receptacle or package that he believes to contain, any article;

(c) where the Authorized Officer is a Superintendent of Health Services or a Medical Officer of Health, examine any books, documents or other records found in any place mentioned in paragraph (a).that he believes to contain any information relevant to the carrying into execution or the enforcement of this Act with respect to any article and make copies thereof or take extracts there- from ; and

(d) seize and detain for such time as may be necessary any article by means of or in relation to which he believes any provisions of this Act or regulations made thereunder have been contravened.

(2) For the purposes of this section and section 23 "article" means-

(a) any cosmetic, device or drug;

(b) anything used or capable of being used for the manufacture, preparation, preservation, packaging or storing of any cosmetic, device or drug; and

(c) any labelling or advertising material.

(3) An Authorized Officer acting under this section shall if so required, produce his authority.

(4) The owner or person in charge of a place entered by an Authorized Officer in pursuance of subsection (1) and every person found therein shall give the Authorized Officer all reasonable assistance in his power and furnish him with such information and such samples as he may require.

(5) No person shall obstruct any Authorized Officer acting in the exercise of his powers under this Act or any regulations made thereunder.

(6) If any Authorized Officer applies to obtain samples of any cosmetic,

device or drug exposed for sale, and the person exposing the cosmetic, device or drug refuses to sell to the Authorized Officer such quantity thereof as he may require or refuses to allow that officer to take the quantity which he is empowered to take as samples the person so refusing shall be deemed for the purposes of subsection (5) to have obstructed an Authorized Officer.

(7) No person shall knowingly make a false or misleading statement either orally or in writing to any
Authorized- Officer engaged in the exercise of his powers under this Act or any regulations made thereunder

(8) No person shall remove or alter, tamper or otherwise interfere in any manner with any article seized under this Act by an Authorized Officer without the authority of the Authorized Officer.

(9) Any article seized under this Act may at the option of the Authorized Officer be kept or stored in the building or place where it was seized or may at his discretion be removed to any other place.

(10) An Authorized Officer shall forthwith inform the Authority of any seizure made under this Act.

Procedure in respect of articles seized.

23. (1) Where an article in. respect of which an offence has been committed is seized under this Act by an
Authorized Officer, such article may be destroyed or otherwise disposed of as the Authority may direct where the Authority is satisfied that there has been a contravention of any of the provisions of this Act or any of the regulations made thereunder and where the owner of such article or the person in possession of such article at the time of seizure consents in writing to the destruction of such article.

(2) Where the owner or person in possession of such article does not consent in writing to the destruction of such article, the Authority-

(a) shall release such article if he is satisfied that the provisions of this Act or any regulation made thereunder in respect of such article have not been contravened; or

(b) shall, where he is satisfied that there has been a contravention of any of the provisions of this Act or regulations made thereunder, forthwith, with notice to such owner or person in possession of the article inform the Magistrate's Court having jurisdiction over the area in which the offence was

committed of the seizure of the article in respect of which the offence was committed.

(3) On information furnished to the court under subsection (2) (b) such court shall-

(a) if, after, trial, it finds the owner or person to possession of the article guilty of contravening any of the provisions of this Act or regulations made thereunder, order that such article be forfeited to the Authority to be disposed of as the court may direct:

Provided, however, that where the offender is not known or cannot be found such article shall be forfeited to the Authority without the institution of proceedings in respect of such contravention; or

(b) if, after trial, it finds the owner or person in possession of the article not guilty of contravening any of the provisions of this Act or regulations made thereunder, order that such article be released to such owner or person in possession.

Analysis

24.(1) An Authorized Officer shall submit any cosmetic, device or drug seized by him or any portion thereof or any sample taken by him, unless destroyed under section 23 (1), to the Approved Analyst for analysis or examination.

(2) Where the Approved Analyst has made an analysis or examination of the cosmetic, device or drug submitted to him under subsection (1), he shall issue a certificate or report to the Authority setting out in that certificate or report the results of his examination or analysis.

(3) For the purposes of this section the Approved Analyst includes an Additional Approved Analyst.

Approved Analyst

25.(1) For the purposes of this Act and the regulations made thereunder the Government Analyst shall be the Approved Analyst.

(2) Notwithstanding the provisions of subsection (1), the Minister may approve any person to be an Additional Approved Analyst. Notification of the approval shall be published in the Gazette.

(3) No person shall be approved as an Additional Approved Analyst-

(a) if he does not possess the prescribed qualifications; or

(b) if that person is engaged directly or indirectly in any trade or business connected with the manufacture, import, sale or distribution of cosmetics, devices or drugs.

Legal Proceedings

Cosmetic Devices and Drugs Technical Advisory Committee

18. (1) There shall be a Committee which shall be called the cosmetics, Devices and Drugs Technical Advisory Committee (hereinafter referred to as the "Committee") consisting of -

(a) the Director of Health Services who shall be the Chairman of the Committee;

(b) the Assistant Director of Health Services in charge of cosmetics , Device and Drugs control Administration who shall be the Secretary of the committee;

(c) the Professor of pharmacology of the University of Colombo;

(d) the pharmacologist of the Medical Research Institute;

(e) the Chairman of the State Pharmaceuticals Corporation;

(f) the Superintendent of the State Medical Stores;

(g) the Government Analyst or any officer nominated by him;

(h) the officer in charge of the Drugs Quality Control Laboratory;

(i) a consultant physician nominated by the Minister;

(j) a consultant surgeon nominated by the Minister;

(k) a representative of the Pharmaceutical Manufacturers' Association nominated by that Association;

(l) a representative of the Bureau of Ceylon Standards, nominated by the Minister in charge of the subject of Industries;

(m) a representative of the Pharmaceutical Society of Sri Lanka nominated by that Society;

(n) a representative of the Sri Lanka Medical Association nominated by that Association; and

(o) a representative of the Independent Medical Practitioners' Association nominated by that Association.

(2) Every member of the Committee nominated under paragraphs (i), (j), (k), (1), (m), (n) or (o) of subsection(1) shall, unless he earlier vacates office by resignation, death or removal, hold office for a period of three years from the data of nomination and shall be eligible for renomination.

(3) Every member of the Committee, other than the members referred to in subsection (2), shall cease to be a member of the Committee on his ceasing to hold office which qualified him to be a member of the Committee.

(4) The Committee may discharge its functions notwithstanding any vacancy among its members.

(5) Five members of the Committee shall constitute a quorum for any meeting of the Committee.

(6) Subject to the provisions of this Act, the Committee may regulate its own procedure in regard to its meetings and the transaction of business at the meetings.

Duties of the committee

19. (1) It shall be the duty of the Committee to advise the Minister on matters arising out of the administration of this Act and to carry out other functions assigned to it under this Act.

(2) The Committee may appoint such sub-committees as it deems fit to exercise such powers or perform such duties as may, subject to such conditions, if any, as the Committee may impose, be delegated to them by the Committee, and may appoint to those sub-committees persons who are not members of the Committee.

Cosmetics Devices and drugs Authority

20. (1) For the purposes of this Act, the Director of Health Services shall be the Cosmetics, Devices and Drugs Authority (hereinafter referred to as the "Authority").

'(2) Every drug shall be registered with the Authority.

(3) The Director of Health Services may with the approval of the Minister

delegate all or any of his powers
as the Authority under this Act to any person by name or office.

Authorised Officers.

21. (1) The Minister may approve any Superintendent of Health Services, any Medical Officer of Health, any Public Health Inspector, any Food and Drugs Inspector and any Drugs Inspector to be an Authorized Officer for the purposes of this Act.

(2) Every Authorized Officer shall exercise the powers of a police officer in terms of the Code of Criminal Procedure Act, No. 15 of 1979, for the purpose of discharging his functions under this Act.

Powers of Authorised Officers.

22.(1) An Authorized Officer may, for the performance of his duties and the exercise of his powers-

(a) at any reasonable time enter any place where he believes any article is manufactured, prepared,
packaged, preserved or stored and examine any such article and take samples thereof, and also
examine anything that he believes is used for the manufacture, preparation, preservation, packaging
or storing of such article;

(b) open and examine any receptacle or package that he believes to contain, any article;

(c) where the Authorized Officer is a Superintendent of Health Services or a Medical Officer of Health, examine any books, documents or other records found in any place mentioned in paragraph (a).that he believes to contain any information relevant to the carrying into execution or the enforcement of this Act with respect to any article and make copies thereof or take extracts there- from ; and

(d) seize and detain for such time as may be necessary any article by means of or in relation to which he believes any provisions of this Act or regulations made thereunder have been contravened.

(2) For the purposes of this section and section 23 "article" means-

(a) any cosmetic, device or drug;

(b) anything used or capable of being used for the manufacture, preparation, preservation, packaging or storing of any cosmetic, device or drug; and

(c) any labelling or advertising material.

(3) An Authorized Officer acting under this section shall if so required, produce his authority.

(4) The owner or person in charge of a place entered by an Authorized Officer in pursuance of subsection (1) and every person found therein shall give the Authorized Officer all reasonable assistance in his power and furnish him with such information and such samples as he may require.

(5) No person shall obstruct any Authorized Officer acting in the exercise of his powers under this Act or any regulations made thereunder.

(6) If any Authorized Officer applies to obtain samples of any cosmetic, device or drug exposed for sale, and the person exposing the cosmetic, device or drug refuses to sell to the Authorized Officer such quantity thereof as he may require or refuses to allow that officer to take the quantity which he is empowered to take as samples the person so refusing shall be deemed for the purposes of subsection (5) to have obstructed an Authorized Officer.

(7) No person shall knowingly make a false or misleading statement either orally or in writing to any
Authorized- Officer engaged in the exercise of his powers under this Act or any regulations made thereunder

(8) No person shall remove or alter, tamper or otherwise interfere in any manner with any article seized under this Act by an Authorized Officer without the authority of the Authorized Officer.

(9) Any article seized under this Act may at the option of the Authorized Officer be kept or stored in the building or place where it was seized or may at his discretion be removed to any other place.

(10) An Authorized Officer shall forthwith inform the Authority of any seizure made under this Act.

Procedure in respect of articles seized.

23. (1) Where an article in. respect of which an offence has been committed is seized under this Act by an
Authorized Officer, such article may be destroyed or otherwise disposed of as

the Authority may direct where the Authority is satisfied that there has been a contravention of any of the provisions of this Act or any of the regulations made thereunder and where the owner of such article or the person in possession of such article at the time of seizure consents in writing to the destruction of such article.

(2) Where the owner or person in possession of such article does not consent in writing to the destruction of such article, the Authority-

(a) shall release such article if he is satisfied that the provisions of this Act or any regulation made thereunder in respect of such article have not been contravened; or

(b) shall, where he is satisfied that there has been a contravention of any of the provisions of this Act or regulations made thereunder, forthwith, with notice to such owner or person in possession of the article inform the Magistrate's Court having jurisdiction over the area in which the offence was committed of the seizure of the article in respect of which the offence was committed.

(3) On information furnished to the court under subsection (2) (b) such court shall-

(a) if, after, trial, it finds the owner or person to possession of the article guilty of contravening any of the provisions of this Act or regulations made thereunder, order that such article be forfeited to the Authority to be disposed of as the court may direct:

Provided, however, that where the offender is not known or cannot be found such article shall be forfeited to the Authority without the institution of proceedings in respect of such contravention; or

(b) if, after trial, it finds the owner or person in possession of the article not guilty of contravening any of the provisions of this Act or regulations made thereunder, order that such article be released to such owner or person in possession.

Analysis

24. (1) An Authorized Officer shall submit any cosmetic, device or drug seized by him or any portion thereof or any sample taken by him, unless destroyed under section 23 (1), to the Approved Analyst for analysis or examination.

(2) Where the Approved Analyst has made an analysis or examination of the cosmetic, device or drug submitted to him under subsection (1), he shall issue

a certificate or report to the Authority setting out in that certificate or report the results of his examination or analysis.

(3) For the purposes of this section the Approved Analyst includes an Additional Approved Analyst.

Approved Analyst

25. (1) For the purposes of this Act and the regulations made thereunder the Government Analyst shall be the Approved Analyst.

(2) Notwithstanding the provisions of subsection (1), the Minister may approve any person to be an Additional Approved Analyst. Notification of the approval shall be published in the Gazette.

(3) No person shall be approved as an Additional Approved Analyst-

(a) if he does not possess the prescribed qualifications; or

(b) if that person is engaged directly or indirectly in any trade or business connected with the manufacture, import, sale or distribution of cosmetics, devices or drugs.

General

Protection for action taken in good faith.

36. Any suit, prosecution or other legal proceeding shall not be instituted against any person for any act which in good faith is done or purported to be done by him under this Act or any regulations made thereunder.

Application of other written law to cosmetics, devices and drugs.

37. (1) The provisions of this Act and any regulations made thereunder relating to drugs which are excisable articles within the meaning of the Excise Ordinance shall be in addition to and not in substitution for the provisions of that Ordinance.

(2) The provisions of the Customs Ordinance shall apply for the purpose of the enforcement, and the prevention and punishment of contravention's or attempted contravention's of the provisions of this Act and any regulations made thereunder relating to the importation of any cosmetic, device or drug.

(3) For the purposes of the application of the Customs Ordinance to any cosmetic, device or drug, the importation of which is prohibited under this Act, such cosmetic, device or drug shall be deemed to be goods the importation

of which is prohibited under that Ordinance.

Regulation

38. (1) The Minister may, after consultation with the Committee, make regulations in respect of matters required by this Act to be prescribed or in respect of which regulations are authorized to be made and in particular in respect of all or any of the following matters:-

(a) declaring that any cosmetic or drug or class of cosmetic or drug is adulterated if any prescribed substance or class of substance is present or has been added to or extracted from or omitted in, that, cosmetic or drug;

(b) the labeling and packaging and the offering, exposing and advertising for sale of any cosmetic, device or drug;

(c) the size, dimensions, fill and other specifications of packages of any cosmetic, device or drug ;

(d) the use of any substance as an ingredient in any cosmetic, device or drug to prevent the user or purchaser from being deceived or misled as to its quality, character, value, composition, or safety or to prevent injury to the health of the user or purchaser;

(e) the standards of composition, strength, potency, purity, quality or other property of any cosmetic, device or drug ;

(f) the method of preparation, the manufacture, preservation, packaging, storing and testing of any, cosmetic, device or drug in the interest of, or for the prevention of injury to, the health of the user or purchaser;

(g) (i) the persons to whom, the circumstances in which, and the terms and conditions subject to which, licenses under this Act may be granted or refused;

(iii) the manner and mode in which applications for licenses under this Act may be made and dealt with; and

(iii) the fee payable for the issue of a license;

(g) requiring persons who manufacture or sell any cosmetic, device, or drug to furnish such information and maintain such books and records as the Minister considers necessary for the proper enforcement and administration of this Act and the regulations made thereunder;

(i) the forms to be used for the purposes of this Act and the regulations made thereunder ;

(j) prohibition and restrictions relating to the sale and transport for sale of any adulterated cosmetic or drug;

(k) the distribution and the conditions of distribution of samples of any drug.

(2) Every regulation made by the Minister shall be published in the Gazette and shall come into operation on the date of publication, or on such later date as may be specified in the regulation.

(4) Every regulation made by the Minister shall as soon as convenient after its publication in the Gazette be brought before Parliament for approval.

(4) Any regulation which is not so approved shall be deemed to be rescinded as from the date of disapproval but without prejudice to anything previously done thereunder.

(5) The date on which any regulation shall be deemed to be so rescinded shall be published in the Gazette.

Savings

39. Notwithstanding the repeal of the Food and Drugs Act, by the Food Act, 1980, the regulations made under that Act and in force immediately before the coming into operation of this Act shall, except where and so far as they are not inconsistent with the provisions of this Act, continue in force until altered, amended, or rescinded by regulations made under this Act.

Interpretation

40. In this Act, unless the context otherwise requires-" adulterated " means the addition of any substance to or substraction of any constituent from a drug or cosmetic so as to affect its quality, composition or potency;

"advertisement" includes any representation by any means whatsoever, for the purpose of promoting directly or indirectly the manufacture, sole or disposal of any cosmetic, device or drug;

"cosmetic" includes any substance or mixture at substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes;

"dentist" means a person for the time being registered as a dentist under the Medical Ordinance ;

"device" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured or sold for use in-

(i) the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state or the symptoms thereof, in man or animal,

(ii) restoring, correcting or modifying a body function or the body structure of man or animal,

(iii) the diagnosis of pregnancy in human beings or animals, or

(iv) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the off-spring and includes a contraceptive device but does not include a drug;

" drug " includes-

(i) any substance or mixture of substances manufactured, sold, offered for sale or represented for use In

(a) the diagnosis, treatment, mitigation or prevention of disease, abnormal physical state or the symptoms thereof in man or animal; and

(b) restoring, correcting or modifying organic functions in man or animal;

(ii) a single drug or combination of drugs ready for use and placed on the market under a special name or in a characteristic form, both patent and proprietary preparations,

but does not include an Ayurvedic drug or Ayurvedic medicine, a Homoeopathic drug or Homoeopathic medicine;

" Government Analyst " means the person for the time being holding the office of the Government Analyst and includes other than for the purposes of section 18, any Additional Government Analyst, Deputy Government Analyst, Senior Assistant Government Analyst or Assistant Government Analyst;

" insanitary conditions " means such conditions or circumstances as are likely to contaminate a cosmetic or drug with dirt or filth or render the same injurious to health;

" label " includes any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to a container of drug, cosmetic or device;

" labelling " includes the label and any written, printed or graphic matter relating to and accompanying the drug, cosmetic or device;

" medical practitioner " means a person registered as a medical practitioner under the Medical Ordinance;

" package " includes anything in which any drug, cosmetic or device is wholly or partly contained, placed or packed;

" sell " means to sell for cash or on credit or by way of exchange and whether by wholesale or retail and

" sale " shall have a corresponding meaning;

" veterinary surgeon " means a person registered as a Veterinary Surgeon or a Veterinary Practitioner under the Veterinary Surgeons' and Practitioners' Act, No. 46 of 1956.

Schedule

SCHEDULE 'A'

Name .. Abbreviation
Pharmacopoeia Internationals .. (Ph.I)
The British Pharmacopoeia .. (B.P.)
The Pharmacopoeia of the United States of America .. (U.S.P.)
The British Pharmaceutical Codex .. (B.P.C.)
The British Veterinary Codex .. (B.V.C.)
The Japanese Pharmacopoeia .. (J.P.)
European Pharmacopoeia ..

SCHEDULE 'B'

lnsulin

Insulin preparations

Anterior pituitary extracts

Radioactive lsotopes

SCHEDULE 'C'

Living vaccines for oral parenteral use Drugs prepared from Mice-organisms or viruses for parenteraluse

Sera and drugs analogous thereto for parenteral use Antibiotics for parenteral use.

SCHEDULE 'D'

Sensitivity discs and tablets

SCHEDULE 'E'

Item No.

1. Thalidomide

2. Lysergic acid diethylamide (LSD) or any salt thereof

3. M, N-Dimethyltryptamine (DET) or any salt thereof

4. N, N-Dimethyltryptamine (DMT) or any salt thereof

5. 4-Methyl-2. 5-dimethoxyamphetamine (STP) (DOM.) or any salt thereof.

SCHEDULE 'F'
Anxiety state Nausea and vomiting in pregnancy
Appendicitis Nocturnal emissions
Arteriosclerosis Obesity
Asthma Oedomatous state
Bladder disease Parangi
Blood poisoning Pleurisy
Cachexia Pneumonia
Cancer Poliomyelitis
Catarrah Rabies
Convulsions Rheumatic fever
Depression Rheumatoid arthritis
Diabetes Sopticoemia
Diptheria Sexual impotency
Disorders of menstruation Sexual underdevelopmcm
Epilepsy Sinusitis
Gall Bladder disease Small pox
Gangrene Spermatorrhoea

Glaucoma Stroke
Goitre Tetanus
Heart Disease Thyroid disease
Hernia Tonsilltis
Hyperteiulon Trachoma
Hypotention Tuberculosis
Impetige Tumours
Infantile Paralysis Ulcer of the gastro interat Intal
Kidney disease Vaginitia
Leprosy Veneral dieseas
Liver disease White Discharge
Locomtor Ataxia Wasting disease
Yawi