PARLIAMENT OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

COSMETICS, DEVICES AND DRUGS ACT, No. 27 OF 1980

[Certified on 17th July, 1980]

Printed on the Orders of Government

Published as a Supplement to Part II of the **Gazette of the Democratic Socialist Republic of Sri Lanka of September 19, 1980**

PRINTED AT THE DEPARTMENT OF GOVERNMENT PRINTING, SRI LANKA

TO BE PURCHASED AT THE GOVT. PUBLICATIONS BUREAU, COLOMBO

Price : Re. 1.55 **Postage : 75 cents**

Cosmetics, Devices and Drugs Act, No. 27 of 1980

[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.

PART I

PROHIBITION IN RESPECT OF COSMETICS, DEVICES AND DRUGS

Licensing of persons and premises for manufacturing &c. cosmetics.

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

(2) 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 of 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.

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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 directions on the label accompanying that device.

Licensing of persons for manufacture &c. of devices.

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

Labelling, 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 device 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 licence issued by the Cosmetics, Devices and Drugs Authority.

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

Probation on manufacture, importation, 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 or 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.

Labelling, 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).

Labelling, &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 in such a manner as is likely to be mistaken for the drug for which the standard is 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 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 manfactured and the process and conditions of manufacture of that drug have been approved in the prescribed form 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, devices and drugs 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'.

PART II

ADMINISTRATION

Cosmetics, 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, Devices 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*), (*l*), (*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 date 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.

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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.

Authorized 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 Authorized 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 therefrom ; 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 in 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.

PART III

Legal Proceedings

Offences.

26. (1) Every person who contravenes any of the provisions of this Act or any regulations made thereunder or fails to comply with any direction given under this Act shall be guilty of an offence and shall be liable on conviction—

(*a*) where the nature of the offence involves injury to the health of the public, to a fine not exceeding five

thousand rupees or to imprisonment for a term not exceeding three years or to both such fine and imprisonment :

(b) for any other offence—

(i) for the first offence to a fine not exceeding one thousand rupees or to imprisonment for a term not exceeding three months or to both such fine and imprisonment ;

(ii) for a second or subsequent offence to a fine not exceeding two thousand rupees or to imprisonment for a term not exceeding six months or to both such fine and imprisonment.

(2) Where a person convicted of an offence under this Act or any regulations made thereunder is convicted of a second or subsequent offence of a like or similar nature under this Act or regulations made thereunder, the court convicting him for the second or subsequent offence may—

(a) cause the name and address of the person convicted and the offence and the punishment imposed for such offence to be published in such newspaper or in such other manner as the court may direct and recover the cost of publication from the person convicted as if it were a fine imposed on him ;

(b) cancel any licence issued to the person convicted for the manufacture, importation, sale and distribution of any cosmetic, device or drug under this Act or any other law and inform the relevant licensing authority accordingly.

Person committing offence to be arrested without a warrant and to be tried by a Magistrate's Court.

27. Every person who commits an offence under this Act or any regulations made thereunder may be arrested without a warrant and every offence under this Act or regulations made thereunder shall be triable by a Magistrate's Court.

Institution of proceedings.

28. A prosecution for an offence under this Act or any regulation made thereunder shall not be instituted—

(a) except by an Authorized Officer ; and

(b) after the expiration of a period of three months from the date of detection of that offence.

Where the accused proves that some other person is guilty of the offence.

29. (1) Where a person (hereinafter referred to as "the accused") is charged with an offence under this Act, he shall, upon complaint duly made by him in accordance with the provisions of section 136 of the Code of Criminal Procedure Act, No. 15 of 1979, and on giving to the prosecution not less than three days' notice of his intention, be entitled to have any other person whom he charges as the actual offender brought before the court, and, if, after the commission of the offence has been proved, the accused proves to the satisfaction of the court that the commission of the offence was due to the act or default of such other person, such other person may be convicted of the offence, and, if the accused further proves that he has used all due diligence to enforce the provisions of this Act, he shall be acquitted of the offence.

(2) Where an accused seeks to avail himself of the provisions of subsection (1)—

(a) the prosecution, as well as the person whom the accused charges with being the actual offender, shall have the right to cross-examine him, if he gives evidence, and any witness called by him in support of his pleas, and to call evidence in rebuttal; and

(b) the court may make such order as it thinks fit for the payment of costs by any party to the proceedings to any other party thereto.

(3) Where it appears to the Authority that an offence has been committed under this Act in respect of which proceedings might be taken under this Act against some person and such Authority is reasonably satisfied that the offence complained of was due to an act or default of some other person and that the first-mentioned person could establish a defence under subsection (1) of this section such Authority may cause proceedings to be taken against that other person without first causing proceedings to be taken against the first-mentioned person.

In any such proceedings the accused may be charged with and, on proof that the offence was due to his act or default, be convicted of the offence with which the first-mentioned person might have been charged.

Defence.

30. (1) In a prosecution for the offence of sale of any cosmetic, device or drug contrary to the provisions of this Act or any regulations made thereunder, subject to subsection (2) it shall be a defence for the accused—

(*a*) that he purchased the cosmetic, device or drug in a package and sold it in the same package and in the same condition that it was at the time he purchased it; and

(*b*) that he could not have with reasonable diligence ascertained that the sale of the cosmetic, device or drug would be in contravention of the Act or any regulations made thereunder.

(2) The defence specified in subsection (1) shall not be available to an accused unless he has within thirty days of the detection of the offence informed in writing the Authorized Officer detecting the offence—

(*a*) of his intention to avail himself of such defence; and

(*b*) the name and address of the person from whom he purchased the cosmetic, device or drug and the date of purchase.

Report or certificate of the Approved Analyst or an Additional Approved Analyst.

31. (1) In the absence of evidence to the contrary, a document purporting to be a report or a certificate signed by the Approved Analyst or an Additional Approved Analyst upon any matter submitted to him for examination or analysis shall be sufficient evidence of the facts stated therein.

(2) When a party against whom a report or a certificate referred to in subsection (1) is produced requests the Approved Analyst or an Additional Approved Analyst, as the case may be, to be summoned as a witness, the court shall summon him on that party paying to the court the expenses of summoning him and shall examine him as a witness.

(3) The report or the certificate referred to in subsection (1) shall not be received in evidence unless the party intending to produce it has given the party against whom it was intended to be produced a copy of the report or the certificate and reasonable notice of his intention to produce it.

Authorized Officer to produce before court the part of the sample retained by him.

32. (1) Where a sample obtained by an Authorized Officer is required to be divided by him into parts, one of which shall be retained by him, the part retained by him shall be produced in court at the time of the institution of the prosecution in relation to such sample.

(2) The Magistrate may of his own motion and shall at the request of any party to the prosecution forward for analysis or examination such part of the sample produced in court under subsection (1) to the Approved Analyst or an Additional Approved Analyst other than an Analyst who has analysed or examined any other part of such sample.

(3) The analyst to whom such part of the sample is forwarded under subsection (2) shall send his report or certificate to the court within twenty eight days of the receipt by him of such part of the sample.

(4) The expenses of the analysis or examination shall be paid by such party as the court may direct.

Copy or extract of document taken by an Authorized Officer.

33. A copy made or extract taken from any book, document or record by an Authorized Officer under sectoin 22 (1) (c) shall, if certified to be a true copy or extract by the Authorized Officer, be admissible in evidence against the person keeping or maintaining that book, document or record or causing that book, document or record to be kept or maintained and shall be prima facie evidence of the contents of that book, document or record.

Presumptions.

34. (1) For the purposes of this Act and of any regulations made thereunder—

(*a*) any cosmetic, device or drug found, kept or exhibited in any shop or other place commonly used for the sale of articles shall be presumed until the contrary is proved to be intended for sale ;

(*b*) any substance capable of being used in the composition or preparation of any cosmetic or drug which is found in premises used in the preparation of cosmetics or drugs shall be presumed until the contrary is proved to be intended for use in the composition or preparation of cosmetics or drugs.

(2) Where in a prosecution for the offence of manufacturing a drug which is adulterated, it is established—

(*a*) that such drug was adulterated with the addition of any other substance ; and

(*b*) that the accused had in his possession or premises such other substance,

it shall be presumed until the contrary is proved that such drug was adulterated by the addition of that other substance.

(3) Where a package containing any cosmetic, device or drug has on or upon it the name and address purporting to be the name or address of the person who manufactured or packaged it, it shall be presumed until the contrary is proved that the cosmetic, device or drug was manufactured or packaged, as the case may be, by the person whose name or address appears on the package.

Offences committed by a body of persons.

35. Where an offence under this Act or any regulations made thereunder is committed by a body of persons then—

(*a*) if that body of persons is a body corporate, every person who at the time of commission of the offence was a director, general manager, secretary or other similar officer of that body ; or

(*b*) if that body is not a body corporate every person who at the time of commission of the offence was a member of that body,

shall be deemed to be guilty of that offence, unless he proves that such offence was committed without his consent or concurrence and that he exercised all such diligence to prevent the commission of such offence as he ought to have exercised in the circumstances having regard to the nature of his functions.

PART IV

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 contraventions or attempted contraventions 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.

Regulations.

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 labelling 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, licences under this Act may be granted or refused ;

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

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

(*h*) 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.

(3) 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 of 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 off-spring, 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 proprietory 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 'A'

Name	*Abbreviation*
Pharmecopoeia Internationlis ..	(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'

Insulin

Insulin preparations

Anterior pituitary extracts

Radioactive Isetopes

SCHEDULE 'C'

Living vaccines for oral parenteral use

Drugs prepared from Mice-organisms or viruses for parenteral use

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

Appendicitis

Arteriosclerosis

Asthma

Bladder disease

Blood poisoning

Cachexia

Cancer

Catarrah

Convulsions

Depression

Diabetes

Diptheria

Disorders of menstruation

Epilepsy

Gall Bladder disease

Gangrene

Glaucoma

Nausea and vomiting in pregnancy

Nocturnal emmissions

Obesity

Oedomatous state

Parangi

Pleurisy

Pneumonia

Poliomyelitis

Rabies

Rheumatic fever

Rheumatoid arthritis

Sopticoemia

Sexual impotency

Sexual underdevelopment

Sinusitis

Small pox

Spermatorrhoea

Stroke

Goitre	Tetanus
Heart Disease	Thyroid disease
Hernia	Tonsilitis
Hypertension	Trachoma
Hypotention	Tuberculosis
Impetige	Tumours
Infantile Paralysis	Ulcer of the gastro intestinal tract
Kidney disease	Vaginitis
Leprosy	Veneral disease
Liver disease	White Discharge
Locomtor Ataxia	Wasting disease
	Yaws