# PARLIAMENT OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

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

[Certified on 17th July, 1980]

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*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.

2—A 49145—11,675 (80/04)

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(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.

2—A 49145—11,675 (80/04)

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 ;

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