The Proposed New National Medicinal Drug, Devises and Cosmetic Authority Draft Bill

“The above bill which is subject to changes from the Cabinet sub Committee on legislation is published herewith for the views of the public. Any fair comment is welcome. (legalunitmoh@gmail.com) in order to formulate this bill in limine with ‘Senaka Bibile Drug Policy’.

A joint seminar is organized with the SLMA and the Ministry of Health on this bill with the view of making awareness and inviting fair comments from the interested parties. This seminar will be held at the Blood Bank Auditorium at Narahenpita at 4.00 p.m. on 06/06/2014.

28.2.2014
L.D.O. 21/2012

AN ACT TO PROVIDE FOR THE ESTABLISHMENT OF A REGULATORY AUTHORITY WHICH SHALL BE RESPONSIBLE FOR THE REGULATION AND CONTROL OF THE MANUFACTURE, IMPORTATION, SALE, STORAGE, DISPOSAL, TRANSPORTATION AND DISTRIBUTION OF MEDICINAL DRUGS IN A MANNER COMPATIBLE WITH THE NATIONAL DRUG POLICY; FOR THE REGULATION AND CONTROL OF THE MANUFACTURE, IMPORTATION, SALE, STORAGE, DISPOSAL, TRANSPORTATION AND DISTRIBUTION OF DEVICES AND COSMETICS; TO PROVIDE FOR THE ESTABLISHMENT OF THE MEDICINAL DRUGS REGULATORY DIVISION, DEVICES REGULATORY DIVISION AND COSMETICS REGULATORY DIVISION; TO REPEAL THE COSMETICS, DEVICES AND DRUGS ACT NO. 27 OF 1980; AND FOR MATTERS CONNECTED THEREWITH OR INCIDENTAL THERETO.

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

1. This Act may be cited as the National Medicinal Drugs, Devices and Cosmetics Regulatory Authority Act, No. of 2014 and the provisions of this Act other than this section, shall come into operation
on such date as the Minister may appoint by Order published in the Gazette (hereinafter referred to as “the appointed date”). The provisions of this section shall come into operation on the date on which this Act becomes an Act of Parliament.

PART I

ESTABLISHMENT OF THE NATIONAL MEDICINAL DRUGS, DEVICES AND COSMETICS REGULATORY AUTHORITY

2. (1) There shall be established an Authority to be known as the National Medicinal Drugs, Devices and Cosmetics Regulatory Authority (hereinafter referred to as the “Authority”) which shall be responsible for the implementation of the provisions of this Act in accordance with the objects set out in section 3.

(2) The Authority shall by the name assigned to it by subsection (1), be a body corporate and shall have perpetual succession and a common seal and may sue and be sued in such name.

PART II

OBJECTS OF THE AUTHORITY

3. The objects of the Authority shall be to –

(a) ensure the availability of safe, efficacious and good quality medicinal drugs, safe, effective and acceptable quality devices and safe and acceptable quality cosmetics to the general public at affordable prices;

(b) function as the central regulator for all matters connected with the importation, manufacture, storage, sale, distribution, exhibition, disposal, transport and registration of medicinal drugs, devices, cosmetics and investigational medicinal products;

(c) ensure through the services provided by National Medicinal Drug Quality Assurance Laboratory and other recognized laboratories, only efficacious, safe and good quality medicinal drugs are made available
to the health care sector and the general public;

(d) ensure that all activities related to importation and
registration of medicinal drugs, devices, cosmetics or
investigational medicinal products are carried out in a
transparent, sustainable and equitable manner;

(e) promote and encourage the manufacturing of
medicinal drugs in Sri Lanka; and

(f) promote the safe and rational use of medicinal drugs
by health care sector and the general public.

4. The Authority shall consist of the following-

(a) ex-officio members -

(i) the Director-General of Health Services;

(ii) the Deputy Director-General of Laboratory
Services; and

(iii) the Secretary to the Treasury or his nominee;

(b) following persons who shall be appointed by the
Minister, (hereinafter referred to as “appointed
members”) -

(i) five specialist clinicians attached to the Ministry of
Health, representing the following clinical
disciplines, nominated by their respective
professional bodies:-

(A) General Medicine;
(B) General Surgery;
(C) Paediatrics;
(D) Gynaecology and Obstetrics; and
(E) Anaesthesiology;

(ii) a Professor of Pharmacology of the
Department of Pharmacology in a Faculty of
Medicine of any University in Sri Lanka established under the Universities Act, No.16 of 1978, nominated by Dean of the respective Faculty of the respective University and appointed in rotation for every three years;

(iii) four persons who are professionals, who have gained eminence in the fields of management, law, accountancy or health.

5. A person shall be disqualified from being appointed, or continuing as a member of the Authority if, he –

(i) is not a citizen of Sri Lanka;

(ii) has been convicted of a criminal offence by a competent court either in Sri Lanka or any other country;

(iii) has declared as bankrupt or an undischarged bankrupt under any law in Sri Lanka or any other country;

(iv) has been within three years prior to his appointment, a member of Parliament;

(v) is a member of the Parliament, a Provincial Council or any Local Authority;

(vi) holds any post in any political party recognized for the purposes of parliamentary elections;

(vii) has any financial or other interest amounting to a conflict of interest, directly or indirectly in any company or undertaking which carries on manufacture, import, sale or distribution of medicinal drugs, devices or cosmetics;
(viii) has been declared by a competent court to be of unsound mind; or

(ix) is removed from office or by resignation or retirement.

6. (1) A member of the Authority may resign from office by letter in that behalf addressed to the Minister, and such resignation shall take effect from the date on which the resignation is accepted in writing by the Minister.

(2) The Minister may remove an appointed member of the Authority from office for reasons assigned.

(3) The term of office of an appointed member of the Authority shall be three years from the date of appointment.

(4) Where an appointed member of the Authority vacates office by death, resignation or other cause, the Minister shall, appoint, having regard to the provisions of section 4, another suitable person in his place, and the person so appointed shall hold office for the remainder of the term of office of the member whom he succeeds.

(5) An appointed member of the Authority whose term of office is due to end, otherwise than by removal, shall be eligible for reappointment for not more than one further term of office.

(6) The Secretary to the Ministry of the Minister to whom the subject of Health is assigned, (hereinafter referred to as “the Secretary”) shall, in consultation with the Minister to whom the subject of Finance has been assigned, determine the remuneration to be paid to the members of the Authority.

7. (1) The Minister shall appoint one of the appointed members referred to in section 4 (b) (iii) to be the Chairman of the Authority (hereinafter referred to as the “the Chairman”).

(2) The Chairman shall at the time of such appointment and during
the tenure of his office, be a fit and proper person who shall not have any interest or any connection with the import, sale or distribution of medicinal drugs, devices, cosmetics or investigational medicinal products regulated by this Act:

Provided that, any person who later acquires any such interest shall become disqualified from being continuing as Chairman.

(3) The term of office of the Chairman shall be three years, and may be eligible for re-appointment unless removed from office on disciplinary grounds.

(4) (a) The Chairman may resign from the office of the Chairman by letter in that behalf addressed to the Minister and such resignation shall take effect from the date on which it is accepted, in writing, by the Minister.

(b) The Chairman shall cease to be the Chairman if he is removed from the office of the Chairman under section 6.

(5) Where the Chairman vacates office by death, resignation or removal, the Minister shall having regard to the provisions of section 4, appoint another appointed person to act in his office. The person so appointed shall hold office for the unexpired period of the term of office of whom he succeeds.

8. (1) The Chairman shall summon all meetings of the Authority. Any member of the Authority may, by written notice, request the Chairman to call a meeting of the Authority and the Chairman shall not refuse to do so, otherwise than for reasonable cause.

(2) The Authority may decide any matter, which is determined by the Chairman to be urgent with the agreement of the majority of the members.

(3) The Chairman shall preside at all meetings of the Authority and in the absence of the Chairman at any such meeting, the members present shall elect a Chairman from among themselves.
(4) The Authority may discharge its functions notwithstanding the existence of any vacancy among its membership.

(5) The quorum for a meeting of the Authority shall be nine members including the Chairman.

(6) All matters for decision by the Authority shall be decided at a meeting of the Authority by the majority of the votes of the members present and voting. The decision supported by the votes of a majority of the members present on any matter, shall be deemed to be the decision of the Authority on that matter.

(7) All decisions of the Authority, supported by reasons, shall be in writing and the seal of the Authority affixed thereto.

(8) In case, there is an equality of votes on any matter to be decided by the Authority, the Chairman of that meeting shall have a casting vote.

(9) Subject to the preceding provisions of this section, the Authority may regulate the procedure in regard to the meetings of the Authority and the transaction of business at such meetings.

(10) No act or decision or proceeding of the Authority shall be invalidated by reason only of the existence of a vacancy among its members or of any defect in the appointment of a member thereof.

9. (1) The Authority may appoint from among its own members or from among persons as it may deem appropriate such number of Committees it considers appropriate for the purpose of assisting it in the exercise of its powers under this Act.

(2) The Authority may, subject to such terms and conditions as it may deem appropriate, delegate to any such Committee, all or any of its powers and functions and any power or function so delegated may be exercised by such Committee in the name and on behalf of the Authority.

(3) Notwithstanding the delegation of all or any of its powers to a
Committee, the Authority may exercise any power so delegated.

10. (1) The powers and functions of the Authority shall be to:

(a) recruit and appoint administrative staff as may be necessary for carrying out the work relating to the administration of the Authority;

(b) appoint sub-committees in consultation with the Secretary;

(c) determine the remuneration payable to the staff of the Authority subject to the approval of the Treasury;

(d) authorize registration and licensing of medicinal drugs, devices, cosmetics or investigational medicinal products and cancel the registration such medicinal drugs, devices, cosmetics or investigational medicinal products in terms of the Act;

(e) regulate the manufacture, importation, promotion, repacking, sale, transportation, distribution, storage, recall and disposal of medicinal drugs, devices, cosmetics or investigational medicinal products;

(f) authorize registration and regulation of pharmacies and medicinal drug stores;

(g) issue licences for manufacture, import, storage, distribution, transport and sale of medicinal drugs, devices, cosmetics or investigational medicinal products and to cancel such licences in terms of the Act;

(h) grant approval for the custom clearance of consignments of medicinal drugs, devices, cosmetics or investigational medicinal products subject to the provisions of this Act and other written laws, if so required by the importers thereof;
(i) conduct awareness programmes in relation to medicinal drugs, devices and cosmetics and post market surveillance on the quality and safety of medicinal drugs, devices, cosmetics or investigational medicinal products which are registered and licensed under the Act;

(j) monitor the usage of medicinal drugs, devices, cosmetics or investigational medicinal products which are registered and licensed under this Act for adverse reactions through use thereof, and to take immediate and necessary action in such an instance;

(k) collect data on quantities of medicinal drugs, devices, cosmetics or investigational medicinal products imported under licences;

(l) collect data on pharmaceutical utilization in Sri Lanka, including data on expenditure of industry and trade, relating to pharmaceutical promotion;

(m) advise the Minister on matters which are required to be prescribed;

(n) acquire, hold, take or give on lease or hire, mortgage, pledge, sell or otherwise dispose of, any movable or immovable property;

(o) issue required correspondence in the custom clearance process of consignments of medicinal drugs, devices, cosmetics or investigational medicinal products; and

(p) review the national drug policy from time to time.

11. (1) The Minister may, from time to time, issue general or special directions to the Authority, in accordance with the Government policy on medicinal drugs, devices or cosmetics.
(2) The Authority shall be subject to any such direction issued by the Minister.

12. (1) The seal of the Authority –

(a) shall be in the custody of such person as the Authority may determine from time to time;

(b) may be altered in such manner as may be determined by the Authority; and

(c) shall not be affixed to any instrument or document except with the sanction of the Authority and in the presence of the Chairman and another member of the Authority who shall sign the instrument or document in token of their presence and such signing shall be independent of the signing of any person as a witness.

(2) The Authority shall maintain a register of the instruments and documents to which the seal of the Authority is affixed.

PART III

APPOINTMENT OF THE EXECUTIVE DIRECTOR

13. (1) The Minister shall in consultation with the Authority appoint a person qualified in the field of medical administration to be the Executive Director of the Authority who shall be the Chief Executive Officer of the Authority.

(2) The Executive Director, subject to such terms and conditions of employment as may be determined by the Authority, carry out all such duties and functions assigned to him by the Authority.

(3) The Executive Director shall be in charge with the general administration of the affairs of the Authority.
(4) The term of office of the Executive Director shall be three years and shall be eligible for re-appointment.

(5) The Authority may remove the Executive Director from office in consultation with the Minister for reasons assigned.

(6) The Executive Director shall not be entitled to be the Chairman of any Committee or sub-Committee appointed under this Act.

(7) Where the Executive Director is temporarily unable to perform the duties of the office due to ill-health, absence from Sri Lanka or for any other cause, the Authority may in consultation with the Minister and having regard to the provisions of subsection (1) of this section, appoint a suitable person to act in his place during such period of absence.

14. (1) (a) The Authority may delegate to the Chairman, the Executive Director or any of the Committee appointed under this Act such of its powers, duties and functions as it may deem necessary, subject to such terms and conditions as it shall specify.

    (b) Notwithstanding any such delegation, the Authority may exercise, perform and discharge any such power, duty or function, and may at any time revoke any such delegation.

(2) (a) The Executive Director may with the approval of the Authority delegate in writing to any officer of the Authority any power or function conferred or assigned to him and such officer shall exercise and discharge any power or function subject to the direction and control of the Executive Director.

    (b) Notwithstanding any such delegation the Executive Director may continue to exercise or discharge any such power or function.

15. (1) The Authority may appoint such officers and servants as it may consider necessary for the efficient discharge of its functions.

    (2) The Authority may, in respect of the officers and servants appointed to the Authority under subsection (1) –
(a) exercise disciplinary control over or dismiss such officers and servants;

(b) fix the rates at which such officers and servants shall be remunerated;

(c) determine the terms and conditions of employment of such officers and servants; and

(d) establish a staff welfare and social security scheme for the benefit of such officers and servants and make contributions to any such scheme.

(3) The Authority may make rules pertaining to all or any of the matters referred to in subsection (2).

16. (1) At the request of the Authority any officer in the public service may, with the consent of that officer and the Secretary to the Ministry of the Minister in charge of the subject of Public Administration, be temporarily appointed to the staff of the Authority for such period as may be determined by the Authority or with like consent, be permanently appointed to such staff.

(2) Where any officer in the public service is temporarily appointed to the staff of the Authority, the provisions of section 14(2) of the National Transport Commission Act, No. 37 of 1991 shall, mutatis mutandis, apply to and in relation to such officer.

(3) Where any officer in the public service is permanently appointed to the staff of the Authority the provisions of section 14 (3) of the National Transport Commission Act, No. 37 of 1991 shall, mutatis mutandis, apply to and in relation to such officer.

(4) Where the Authority employs any person who has entered into a contract with Government by which he has agreed to serve the Government for a specified period, any period of service to the Authority by that person shall be regarded as service to the Government for the purpose of discharging the obligation of the such contract.
PART IV

FINANCE

17. (1) The Authority shall have its own Fund, (hereinafter referred to as “the Fund”).

(2) There shall be paid into the Fund of the Authority –

(a) all such sums of money as may be voted from time to time by Parliament for the use of the Authority;

(b) all such sums of money as may be received by the Authority by way of fees or otherwise in the discharge of its functions;

(c) sixty percentum of the money collected as fines imposed for the commission of any offence under this Act;

(d) all such sums of money as are credited or transferred to the Fund; and

(e) all such sums of money as may be made available to it by way of grant or donations.

(3) There shall be paid out of the fund –

(a) remuneration payable to the members and the staff of the Authority;

(b) such sums as the Authority may consider necessary for the promotion, assistance and encouragement of rational use of medicinal drugs and devices among medical practitioners and for the promotion of knowledge of such medicinal drugs and devices and
good pharmacy practices among pharmacists and activities related to pharmaco-vigilance;

(c) such sums as the Authority may consider necessary for consumer education and the dissemination of information relating thereto and for any purpose connected with or incidental to the furtherance of such education; and

(d) such sums of money as may be required to defray the expenses incurred by the Authority in the exercise, discharge and performance of its powers, functions and duties under this Act.

18. (1) The financial year of the Authority shall be the calendar year.

(2) The Authority shall cause proper books of accounts to be kept of its income and expenditure, assets and liabilities and all other transactions of the Authority.

(3) The accounts of the Authority shall be audited annually by the Auditor General or a qualified auditor appointed by Auditor General in terms of Article 154 of the Constitution.

(4) For the purpose of this section “qualified auditor” means-

(a) an individual who, being a member of the Institute of Chartered Accountants of Sri Lanka or of any other Institute established by law, possesses a certificate to practice as an Accountant, issued by the Council of such Institute; or

(b) a firm of Accountants, each of the resident partners of which, being a member of the Institute of Chartered Accountants of Sri Lanka or of any other Institute established by law, possesses a certificate to practice as an Accountant, issued by the Council of such Institute.

19. (1) The Authority shall annually prepare a written report of the Authority’s work during the year completed, and shall transmit to the
Minister-

(a) a copy of such report; and

(b) a copy of the income and expenditure account and balance sheet in respect of such year certified by the Auditor- General.

(2) The Minister shall lay copies of the report and statements referred to in subsection (1) before Parliament.

PART V

MEDICINAL DRUGS, DEVICES AND COSMETICS TECHNICAL ADVISORY COMMITTEE

20.(1) The Authority shall appoint a Committee which shall be known as the Medicinal Drugs, Devices and Cosmetics Technical Advisory Committee (hereinafter referred to as the “the TAC”) consisting of -

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

(b) the Deputy Director- General of Laboratory Services of the Ministry of Health;

(c) the Deputy Director of Medical Technology and Supplies who shall be the Secretary of the Committee nominated by the Director General of Health Services;

(d) the Professor of Pharmacology of any University, established under the Universities Act, No.16 of 1978 who shall not be a member of the Authority nominated by the Minister;
(e) the Pharmacologist of the Medical Research Institute nominated by the Director of such Medical Research Institute;

(f) the Chairman of the State Pharmaceutical Corporation established under the State Industrial Corporation Act, 49 of 1957;

(g) the Director of the Medical Supplies Division of the Ministry of Health;

(h) a representative of the Government Analyst, nominated by the Government Analyst;

(i) the Director of National Drug Quality Assurance Laboratory;

(j) a representative of the Director General of Customs appointed under the Customs Ordinance (Chapter 235), nominated by the Director General of Customs;

(k) the Director General of the Sri Lanka Standard Institution established under the Sri Lanka Standard Institution Act, No. 6 of 1984;

(l) the Chief Legal Officer of the Ministry of Health;

(m) a Consultant Physician, nominated by the College of Physicians of Sri Lanka;

(n) a Consultant Surgeon nominated by the College of Surgeons of Sri Lanka;

(o) a Consultant Pediatrician nominated by the College
of Pediatricians of Sri Lanka;

(p) a Consultant Obstetricians and Gynecologists nominated by College of Obstetricians and Gynecologists of Sri Lanka;

(q) a representative of the Sri Lanka Medical Association;

(r) a representative of the Attorney General’s Department, nominated by the Attorney General;

(s) a representative of the Pharmaceutical Manufacturer’s Association, nominated by that Association;

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

(u) a representative of the Independent Medical Practitioners’ Association, nominated by that Association;

(v) a representative of the College of General Practitioners’ of Sri Lanka, nominated by that College;

(w) a representative of the Sri Lanka Dental Association, nominated by that Association; and

(x) a representative of the Sri Lanka Chamber of the Pharmaceutical Industry, nominated by that Chamber.

(2) Every member of the TAC nominated under paragraphs (m), (n), (o), (p), (q), (r ), (s) (t), (u), (v), (w) and (x) of subsection (1) shall, unless earlier vacates office by resignation, death or removal, hold office for a period of three years from the date of appointment and shall be
eligible for re-appointment.

(3) The TAC may discharge its functions notwithstanding any vacancy among its membership.

(4) The quorum for any meetings of the TAC shall be eleven members.

(5) Subject to the provisions of this Act, the TAC may regulate its own procedure in regard to its meetings and transactions of business at such meetings.

Functions of TAC.

21. (1) The function of the TAC shall be to advise the Minister and the Authority on the matters relating to registration, quality assurance, regulation of promotion and monitoring of the rational use of medicinal drugs, devices and cosmetics when required by the Minister or the Authority.

(2) The Authority in consultation with TAC may appoint such number of sub-Committees on Medicinal Drugs, Devices, Cosmetics, Advertising and Defective medicinal drugs review or any other subject matter as may be required for the implementation of its functions.

(3) The TAC may from time to time invite distinguished local or foreign persons of having eminent professional background to serve as experts of the Authority.

PART VI
LICENSING AND REGISTRATION

22. (1) No person shall manufacture or import any medicinal drug, device or cosmetic without obtaining a licence from the Authority and without being registered with the Authority for that purpose under this Act.

(2) No person shall store, sell, re-pack, assemble, distribute or transport any medicinal drug, device or cosmetic without obtaining a licence therefor from the Authority.
(3) (a) The provisions of sub sections (1) and (2) shall not apply to any patient who needs for his personal medication a medicinal drug, cosmetic or device which is not registered under the Act.

(b) Such person may import such medicinal drug, device or cosmetic on a prescription issued by the medical practitioner treating him, with the prior approval of the Authority.

(4) No person shall manufacture or prepare, store or sell any medicinal drug, device or cosmetics in any premises unless such premises has been licensed in that regard by the Authority:

Provided that the provisions of subsection (4) shall not apply to any premises which is used for retail sale of cosmetics if such cosmetic is not required to be registered under this Act or any other written law.

Issue of Licence.

23. Every licence granted under this section shall –

(a) be in such form as may be prescribed;

(b) unless it is cancelled earlier, be in force for a period as may be specified in such licence.

Refusal to issue a licence.

24. In the event the Authority refuses to issue a licence, it shall cause its decision to be communicated to the applicant who shall be entitled to appeal from such decision within fourteen days from the date of receipt of such decision to the Appeal Committee referred to in section 83.

Suspension or revocation of licence.

25. (1) A licence already issued may be suspended or revoked by the Authority in case of non-compliance with the prescribed conditions.

(2) An applicant may at any time withdraw an application that is not yet approved by notifying the Authority in writing, without prejudice to his right to re-apply for a licence.
PART VII

REGULATION AND CONTROL OF ALL ACTIVITIES RELATING TO MEDICINAL DRUGS

26. (1) No person shall manufacture, prepares, preserve, re-pack, package or store any medicinal drug under insanitary conditions.

(2) No person shall import, distribute or exhibit any medicinal drug that –

(a) was manufactured, prepared, preserved, packaged or stored 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 medicinal drug is used –

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

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

(d) is adulterated; or

(e) is different to the character, value, potency, quality, composition or dosage of the medicinal drug contained in the prescription;

27. (1) A Pharmacist shall be present in every Pharmacy or drug store and registration of such Pharmacy or drug store shall be as prescribed. The Authority may inform the Medical Council, of the
registration of Pharmacies and drug stores and maintain a register to that effect.

(2) The Pharmacist shall before the sale of every medicinal drug inform the buyer the cost of such medicinal drug.

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

(2) Where a standard has not been prescribed for any medicinal drug, but a standard for that medicinal drug is contained in any publication prescribed by regulations, no person shall label, package, sell, exhibit, distribute or advertise any medicinal drug which does not conform to the standard contained in that publication or in such a manner as is likely to be mistaken for the medicinal drug which the standard is contained in that publication.

(3) Where a standard has not been prescribed for any medicinal drug, or a standard for that medicinal drug is not contained in any prescribed publication, no person shall sell, exhibit or distribute such medicinal drug –

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

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

29. No person shall sell, exhibit or distribute any medicinal drug as may be prescribed by regulations unless the premises in which the medicinal drug was manufactured and the process and conditions of manufacture of that medicinal drug have been approved in the prescribed form and manner as being suitable to ensure that the medicinal drug will be safe for use.
30. No person shall sell, exhibit or distribute any medicinal drug as may be prescribed by regulations unless the batch from which that medicinal drug was taken has been approved in the prescribed form and manner as reliable for use.

31. No person shall manufacture, import, store, sell, re-pack, distribute, transport, exhibit or have in his possession any medicinal drug which is not safe for general use, as may be prohibited by regulations.

32. (1) No person shall, without prior written approval of the Authority, advertise any medicinal drug to the public as a treatment, prevention or cure for any of the diseases, disorders or abnormal physical states as may be prescribed.

(2) No person shall import, sell, re-pack, or distribute any medicinal drug which is –

(a) represented by a label; or
(b) advertised to the public,

as a treatment, prevention or cure for any of the diseases, disorders or abnormal physical states prescribed under subsection (1).

33. No person other than the persons as may be prescribed by regulations shall obtain or have in his possession any prohibited medicinal drug.

34. (1) No person shall label, package, re-pack, treat, process sell, distribute, exhibit or advertise any medicinal 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 medicinal drug that is not labeled or packaged in a manner as may be prescribed by the regulations made under this Act shall be deemed to be labeled or packaged contrary to subsection (1).
35. (1) No person shall distribute or cause to be distributed any medicinal drug as a Physician’s sample to the general public:

Provided that the preceding provision shall not apply to the distribution of any sample of a medicinal drug by a medical practitioner, dentist or veterinary surgeon to a patient of such medical practitioner, dentist or veterinary surgeon.

(2) No person shall exhibit or store any medicinal drug marked as a Physician’s sample.

(3) The provisions of sub section (2) shall not apply to any representative of a company duly authorized by the Authority.

36. (1) No person shall import or accept as a donation any medicinal drug for free distribution or to promote within Sri Lanka, without the authority of a license issued by the Authority in that behalf.

(2) Any person who contravenes the provisions of subsection (1) commits an offence and shall on conviction by a Magistrate’s Court after summary trial be liable to a fine not exceeding one million rupees or an imprisonment of either description for a period not exceeding five years or to both such fine and imprisonment.

37. (1) The Authority shall, where the Authority finds that any medicinal drug, device or cosmetic does not meet the required standard or that medicinal drug, device or cosmetic as manufactured would cause serious health problems to the person using, issue an order requiring the importer, manufacturer, trader or distributor of that medicinal drug, device or cosmetic to—

(a) cease the distribution immediately;

(b) withdraw from sale or use;

(c) notify immediately the health professionals and users to cease using of;

(d) dispose according to prescribed methods,
such medicinal drug, device or cosmetic.

(2) The Authority shall cause notice of the ban or withdrawal from use of medicinal drugs, devices or cosmetics in terms of this section, to be published in the daily newspaper or website of the Ministry or broadcast over any electronic media.

(3) Any person who contravenes the provisions of subsection (1) commits an offence and shall on conviction by a Magistrate’s Court after summary trial, be liable to a fine not exceeding one hundred thousand Rupees or an imprisonment of either description for a period not exceeding three years or to both such fine and imprisonment.

**38.** (1) Every Medical Practitioner, Dentist or Veterinary Surgeon shall write in the prescription given by him, the generic name as well as the brand name, of any medicinal drug prescribed by him:

Provided that in relation to a combined medicinal drug where generic version of a medicinal drug is not available such Medical Practitioner, Dentist or Veterinary Surgeon may write the brand name of such medicinal drug in the prescription given by him.

(2) Where the brand name of a medicinal drug which is prescribed as above is not available, the Pharmacist may dispense any other brand of the same (generic) medicinal drug with the consent of the buyer.

(3) Where the number of drugs available are under the (same) generic name of different brand names of the medicinal drug, the Pharmacist shall, inform the buyer the cost of each such drug and give him the choice of buying the drug of his preference.

**39.** (1) There shall be established a body to be known as the Medical Technology and Supplies Directorate (hereinafter referred to as “the MTSD”).

(2) The Medical Technology and Supplies Directorate functioning as the MTSD on the appointed date, under the Ministry of the Minister
shall be deemed to be the MTSD established under subsection (1) and such MTSD shall on and after the appointed date carry out the functions as specified in this Act.

(3) The MTSD shall also carry out the functions assigned to it from time to time by the Authority.

(4) The Director who is in charge of the MTSD on the date immediately preceding the appointed date shall be in charge of the MTSD established under sub section (1).

PART VIII

ESTABLISHMENT OF THE MEDICINAL DRUGS REGULATORY DIVISION

40. (1) There shall be established for the purposes of this Act a Division within the MTSD of the Ministry of Health, to be known as the Medicinal Drugs Regulatory Division (hereinafter referred to as “the MDR Division”).

(2) There shall be a person appointed by the Secretary from among persons having knowledge in Pharmacology to be in charge of the MDR Division who shall function as a Director under this Act.

(3) The principal function of the MDR Division shall be to co-ordinate all activities in respect of medicinal drugs.

(4) The MDR Division shall communicate to the Authority through the Head of the MDR Division its recommendations in relation to each application for a registration of medicinal drugs in Sri Lanka taking into consideration the evaluation of the Medicinal Drugs Evaluation Committee referred to in section 43.

41. The MDR Division shall have under its supervision and control,
such number of sub-divisions as may be required for the implementation of its functions relating to registration, quality assurance, regulation of promotion and monitoring of the rational use, determination of a pricing mechanism for medicinal drugs and the registration of retail outlets, wholesale outlets, distributors and manufacturers of medicinal drugs.

42. The Secretary may appoint such number of Deputy Directors, Assistant Directors and other officers and advisers as are necessary for the discharge of the functions of the MDR Division and they shall be remunerated at such rates as may be determined by the Secretary, in consultation with the Secretary to the Ministry of the Minister to whom the subject of Finance is assigned.

43. (1) There shall be appointed for the purposes of this Act a Committee which shall be known as the Medicinal Drugs Evaluation Committee (hereinafter referred to as “the MDEC”).

(2) The principal function of the MDEC shall be to carry out the technical evaluation of the samples of medicinal drugs submitted with the application for registration and submit a report in respect thereof to the Authority.

(3) The report shall specify the benefits and risks attached to such medicinal drugs, and the efficacy and cost effectiveness of such drug in keeping with the national policy.

(4) The MDEC shall consist of the following persons who shall be appointed by the Authority in consultation with the Secretary, -

(a) ex-officio members-

(i) the Deputy Director - General of Laboratory Services of the Ministry;

(ii) the Director of Medical Technology and Supplies of the Ministry;

(iii) the Director of Medical Supplies Division of the Ministry;
(iv) the Director of National Drug Quality Assurance Laboratory of the Ministry;

(v) the Chairman of State Pharmaceutical Corporation or his nominee;

(vi) the Chief Epidemiologist of the Epidemiology Unit of Colombo;

(b) nominated members –

(i) five specialist clinicians attached to the Ministry of the Minister representing the following fields nominated by their respective professional bodies–

(A) General Medicine;

(B) General Surgery;

(C) Pediatrics;

(D) Gynecology and Obstetrics; and

(E) Anestheology;

(ii) the Professor of Pharmacology of a Faculty of Medicine of any University established under the Universities Act, No. 16 of 1978 nominated by the Director-General of Health Services;

(iii) a Pharmacist nominated by the Director-General of Health Services.

(5) (a) There shall be appointed a panel of experts from among whom the Director may co-opt additional members to the MDEC as and when necessary, depending on the subject matter dealt with by the MDEC.

(b) The members who are co-opted shall be present at all meetings for which their presence is required, but they shall have no voting rights at such meetings.
(6) The Director of Laboratory Services shall function as the Chairman of the MDEC. In the absence of the Director of Laboratory Services, the Deputy Director of Medical Technology and Supplies shall function as the Chairman.

(7) The term of office of a nominated member shall be three years.

44. (1) There shall be established a body to be known as the National Drug Quality Assurance Laboratory (hereinafter referred to as “the NDQAL”), which shall function as the National Laboratory for the Quality Assurance of Medicinal Drugs, Devices and Cosmetics.

(2) The NDQAL which is functioning as the National Drug Quality Assurance Laboratory on the appointed date of this Act, under the Ministry of the Minister shall be deemed to be the NDQAL established under subsection (1) and such NDQAL shall on and after the appointed date of this Act carry out the functions as specified in this Act with no diminution in the terms of service enjoyed by such officers on the day immediately preceding the appointed date of this Act.

(3) The NDQAL shall also carry out the functions and duties assigned to it from time to time by the Authority.

(4) The person in charge of the NDQAL shall be the Director.

45. (1) The functions of the NDQAL shall be :-

(a) testing of the medicinal drugs, devices or cosmetics available in the country and expected to be available in the country including the articles:-

(i) submitted with the application for registration;

(ii) collected at the entry to the country;

(iii) submitted as a complaint by users;
(iv) collected during the post marketing surveillance by NDQAL;

(v) submitted by the Authority;

(b) to charge fees with the approval of the Secretary for testing of medicinal drugs, devices or cosmetics submitted by the importers or manufacturers except where such medicinal drug, device or cosmetic were submitted following a complaint by a user; and

(c) to function, as an additional approved Government Analyst, when the circumstances so require.

(2) The final analysis of the Director NDQAL on the standard of any medicinal drug or device forwarded to him for any testing or analysis, shall be final.

(3) The Director shall carry out any testing or analysis under this section based on acceptable technical evidence.

46. (1) (a) The Authority shall from time to time issue general guidelines to the MDEC relating to matters connected with the evaluation of medicinal drugs submitted to it and such other items which come within its purview.

(b) These guidelines issued under paragraph (a) may direct the MDEC to consider during its process of evaluation, the quality, safety, efficacy, need, cost effectiveness and the cost of each medicinal drugs and related item submitted to it.

(2) The guidelines issued in terms of subsection (1) shall be based on the Good Manufacturing Practices Guidelines (GMP) may be reviewed and revised from time to time in order to maintain parallels.
with internationally accepted standards and practices.

(3) The MDEC shall, based on the general guidelines issued by the Authority, determine the process of evaluation which is to be followed in the evaluation of each medicine and related item.

(4) The Minister may make regulations-

(a) setting out the procedures to be followed, including specified time-limits for the conduct of such evaluation; and

(b) to give effect to the Code containing Good Manufacturing Practices Guidelines (GMP).

PART IX
PROCEDURE FOR REGISTRATION OF MEDICINAL DRUGS

47. (1) Any person who wishes to sell, import, manufacture, prepare, preserve, package, store or distribute any medicinal drug shall make an application for the registration and licensing in such medicinal drugs in the prescribed form to the MDR division.

(2) The application shall be accompanied by the prescribed particulars, the samples of the medicinal drug and the prescribed fee.

(3) The Director shall maintain a Register in which every application received for the registration and licensing of a medicinal drug shall be recorded. The particulars to be entered in such Register shall be as prescribed.

(4) The Director shall upon receipt of such application submit it together with the sample of the medicinal drug and all the particulars,-

(a) to the MDEC, for the evaluation of the application and the medicinal drug considering the necessity to ensure the availability of efficacious, safe and good quality medicinal drugs relevant to the healthcare needs of the citizens at an affordable price; and
(b) to the NDQAL, along with the sample of the drug for evaluation of the quality and the efficacy of the medicinal drug to which such sample relates.

(5) The Director shall inform the Authority and the applicant in writing that the application has been received and submitted to the MDEC and the NDQAL.

(6) The Minister may make regulations-

   (a) setting out the procedures to be followed, by the MDEC and the NDQAL in their respective evaluation processes;

   (b) specifying-

      (i) the time-limits in conducting such evaluation;

      (ii) the manner in which the MDEC to conduct its meetings and the procedure to be followed at such meetings; and

      (iii) the matters which should be included in the reports to be submitted.

(7) (a) The Authority may direct the MDEC and the NDQAL to finalize the evaluation process within a specified time period where the medicinal drug is essential for national health.

   (b) The MDEC and the NDQAL shall within the time limits specified submit their report on such evaluation to the Director unless there are compelling reasons for any delay.

48. Where all the requirements of the preceding sections of the Act are complied with to the satisfaction of the MDR Division and the report of the MDEC and NDQAL and the evaluation of the Panel of Experts, if
any, have been obtained, the MDR Division shall forward to the Authority along with all the prescribed documents, its recommendation in respect of the application.

49. (1) (a) The Authority shall upon taking into consideration the recommendations submitted by the MDR decide whether to register such medicinal drug or not, within one month of the date of receipt of such recommendations.

(b) The Authority may where necessary, call for clarifications from the MDEC or any other experts, with regard to the report of the MDEC and the NDQAL.

(2) The Authority may where no such clarification is required, register the medicinal drug and inform the applicant of such registration in writing and may inform the public of such registration by order published in the Gazette.

(3) (a) The Authority may refuse to grant the registration even where the MDR Division recommends the application, in respect of such medicinal drug for reasons assigned therefor in writing.

(b) Where the Authority refuses to grant the registration in respect of such medicinal drug such refusal shall be informed to the applicant within one week of taking such decision.

(4) (a) The Authority where it decides to grant the registration in respect of any medicinal drug, shall issue a Certificate of Registration to the applicant who shall, hereinafter in this part, be referred to as “the holder of Certificate”.

(b) The Certificate of Registration shall include the purpose for which the registration is granted, its period of validity and the terms and conditions applicable thereto.

(5) Any registration granted under this section, including medicinal drugs already registered shall be valid for a period mentioned in such Certificate of Registration and may be made subject to such
conditions as may be determined by the Authority in accordance with the provisions of this Act.

(6) Upon obtaining the Certificate of registration, the applicant shall enter into an agreement with the Authority to the effect that he shall inform the Authority of any new side effects, cautions, contraindications or removal of any indications due to new facts within two weeks of such facts being revealed.

50. (1) The holder of a Certificate may apply to the Authority, for renewal of such registration six months prior to the date of expiry of such registration.

(2) The application for such renewal of registration shall be in the prescribed form and shall be accompanied by the prescribed fee.

(3) The Authority shall, upon receiving such application for renewal, submit the application to the MDEC for its opinion.

(4) The MDEC may, through the Authority, request for samples, documents or any other evidence, which it deemed necessary, from the applicant or any other party for the purpose of evaluation of the medicinal drug for the renewal of registration.

(5) The Authority may renew the registration for a further period of two years where the Authority is satisfied with the reasons set out in the application for renewal of registration.

51. (1) Where the Authority is of the opinion that-

(a) the holder of Certificate has failed to comply with any condition subject to which any medicinal drug has been registered;

(b) the medicinal drug does not comply with any prescribed requirement;

(c) it is not in the public interest that the medicinal drug
shall be available;

(d) the medicinal drug has been imported to Sri Lanka before the lapse of one year from the registration of importation;

(e) the holder of Certificate has failed to comply with any direction of the Authority; or

(f) the holder of Certificate has violated any provision of this Act or any regulation made thereunder,

the Authority shall cause notice of cancellation or suspension to be issued to the holder of the Certificate in respect of such medicinal drug.

(2) Any such notice shall specify the grounds on which the Authority’s opinion is based, and shall indicate that the holder of Certificate may within one month after receipt thereof submit to the Authority in writing any comments he may wish to forward in respect thereof.

(3) Where the holder of Certificate fails to submit his comments within the time assigned therefor or after consideration of any comments submitted the Authority is of the opinion that the registration of the medicinal drug in question shall be suspended or cancelled, the Authority shall suspend or cancel the Certificate and inform in writing of such suspension or cancellation to the holder of Certificate immediately.

(4) Where the holder of Certificate, does not apply for a renewal of such Certificate six months before its expiry date, the registration of the medicinal drug which such Certificate relates, shall be deemed to have automatically been cancelled.

52. (1) The provisions of the Consumer Affairs Authority Act, No. 9 of 2003 shall apply in respect of the pricing of medicinal drugs under this Act.

(2) The Consumer Affairs Authority shall consult the Authority in
determining the prices of such medicinal drugs in order to ensure the introduction of a transparent pricing system for all the medicinal drugs sold in Sri Lanka which are registered under this Act.

53. (1) The Authority may grant permission in special circumstances such as to save a life, to improve the quality of life or to control an outbreak of an infection or an epidemic or any other national emergency or for national security to import and supply a particular medicinal drug in specified quantities.

(2) Such permission may be granted :-

(a) on a request made by the Ministry of Health; or

(b) on appeal made by an individual or an organization recommended by the Ministry of Health.

(3) The importer shall be responsible for the management and regulation of the medicinal drugs imported under this section and reporting back to the Authority.

PART X

REGULATION AND CONTROL OF ALL ACTIVITIES RELATING TO DEVICES

54. No person shall manufacture, import, assemble, sell 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.

55. No person shall manufacture, import, sell, transport, assemble
or distribute any device without the authority of a licence issued by the Authority.

56. No person shall label, package, treat, process, sell, assemble, distribute or advertise any device in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its safety and effectiveness.

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

58. (1) No person shall without prior written approval of the Authority advertise any device to the public as a treatment, prevention or cure for any of the diseases, disorders, or abnormal physical states as may be prescribed.

(2) No person shall import, sell or distribute any device that is

(a) represented by a label; or

(b) advertised to the public,

as a treatment prevention or cure for any of the diseases, disorders or abnormal physical states prescribed under subsection(1).

59. No person other than the persons as may be prescribed by regulations shall obtain or have in his possession any prohibited device which is not safe for general use.

60. (1) There shall be established for the purposes of this Act a Division within the MTSD of the Ministry of Health, to be known as the Devices Regulatory Division (hereinafter referred to as the “DR Division”).

(2) There shall be a person appointed by the Secretary from among persons having knowledge in Devices to be in charge of the DR Division who shall function as a Director under this Act.
(3) The principal function of the DR Division shall be to co-ordinate all activities in respect of Devices.

(4) The DR Division shall communicate to the Authority through the Head of the DR Division its recommendations in relation to each application for a registration of Devices in Sri Lanka taking into considered the evaluation of the Devices Evaluation Committee referred to in section 63.

61. The DR Division shall have under its supervision and control, such number of sub-divisions as may be required for the implementation of its functions relating to registration, quality assurance, regulation of promotion and monitoring of the rational use, determination of a pricing mechanism for devices and the registration of retail outlets, whole sale outlets, distributors and manufacturers of devices.

62. The Secretary may appoint such number of Deputy Directors, Assistant Directors and other officers and advisers as are necessary for the discharge of the functions of the DR Division and they shall be remunerated at such rates as may be determined by the Secretary in consultation with the Secretary to the Ministry of the Minister to whom the subject of Finance is assigned.

63. (1) There shall be appointed for the purposes of this Act a Committee which shall be known as the Devices Evaluation Committee (hereinafter referred to as “the DEC”).

(2) The principal function of the DEC shall be to carry out the technical evaluation of the sample of a device submitted with the application for registration and submit a report in respect thereof to the Authority.

(3) The report shall specify the benefits and risks attached to such device, and the cost effectiveness of such device in keeping with the national policy.

(4) The DEC shall consist of the following persons who shall be appointed by the Authority in consultation with the Secretary, -

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(c) ex-officio members-

(i) the Director of Laboratory Services of the Ministry;

(ii) the Deputy Director - General (Dental Services) of the Ministry;

(iii) the Deputy Director - General (Biomedical Engineering) of the Ministry;

(iv) the Secretary of Medical Drugs Evaluation Committee of the Ministry;

(v) the Deputy Director Medical Technology and Supplies of the Ministry;

(vi) the Director of Sexually Transmitted Disease / Acquired Immunodeficiency Syndrome Control Programme;

(vii) the Director of National Drugs Quality Assurance Laboratory;

(viii) the President of Collage of Ophthalmologists;

(ix) the Deputy General Manager (Technical and Laboratory) of State Pharmaceutical Corporation;

(x) the Manager (Technical) of the State Pharmaceuticals Corporation;

(d) nominated members-

(i) the Professor of Pharmacology, Faculty of Medicine, from any University established under the Universities Act, No. 16 of 1978, nominated by the Director General of Health Services;
(ii) a Consultant in Transfusion Medicine or an Assistant Director of National Blood Transfusion Services, nominated by the Director General of Health Services;

(iii) a Consultant Epidemiologist, nominated by the Director General of Health Services, in consultation with the Epidemiological Unit;

(iv) a Consultant General Surgeon, nominated by the Director General of Health Services, in consultation with the College of Surgeons;

(v) a Consultant Community Physician, nominated by the Director General of Health Services, in consultation with the College of Community Physicians;

(vi) a Consultant Virologist, nominated by the Director General of Health Services, in consultation with the College of Microbiologists;

(vii) a Consultant Biochemist, nominated by the Director General of Health Services in consultation with the Association of Biochemists;

(viii) a Consultant Pathologist, nominated by the Director General of Health Services, in consultation with the College of Pathologists;

(ix) a Consultant Pediatrician, nominated by the Director General of Health Services, in consultation with the College of Pediatricians;

(x) a Consultant Anesthesiologist, nominated by the Director General of Health Services, in consultation with the College of Anesthesiologists;
(xi) an Oral Maxillo Facial Surgeon, nominated by the Director General of Health Services, in consultation with the College of Dental Surgeons;

(xii) an Assistant Director of Sri Lanka Standards Institute established under the Sri Lanka Standards Institute Act, No. 6 of 1984, nominated by the Director General of Sri Lanka Standards Institute;

(xiii) an Assistant Director of Medical Supplies Division, nominated by the Director General of Health Services, in consultation with the Director of Medical Supplies Division;

(xiv) a representative of Sri Lanka Dental Association, nominated by that Association.

(5) (a) There shall be appointed a panel of experts from among whom the Director may co-opt additional members to the DEC as and when necessary, depending on the subject matter dealt with by the DEC.

(b) The members who are co-opted shall be present at all meetings for which their presence is required, but they shall have no voting rights of such meeting.

64. (1) (a) The Authority shall, from time to time, issue general guidelines to the DEC relating to matters connected with the evaluation of devices submitted to it and other items which comes within its purview.

(b) These guidelines issued under paragraph (a) may direct the DEC to consider during its process of evaluation, the quality, safety, efficacy, need, cost effectiveness and the cost of each device and any related item submitted to it.

(2) The guidelines issued in terms of subsection (1) shall be based on the Good Manufacturing Practices Guidelines (GMP) and may be reviewed and revised from time to time in order to maintain parallels with internationally accepted standards and practices.
(3) The DEC shall, based on the general guidelines issued by the Authority, determine the process of evaluation which is to be followed in the evaluation of each device and related item.

(4) The Minister may make regulations setting out the procedures to be followed, including, specified time-limits for the conduct of the evaluation.

65. (1) Any person who wishes to sell, import, manufacture or distribute any device shall make an application for registration and licensing of such device in the prescribed form to the DR division.

(2) The application shall be accompanied by the prescribed particulars, the sample of the device and the prescribed fee.

(3) The Director shall maintain a Register in which every application received for the registration and licensing of a device shall be recorded. The particulars to be entered in such Register shall be as prescribed.

(4) The Director shall, upon receipt of an application, submit it together with the sample of the device and all other necessary particulars,-

(a) to the DEC, for evaluation of the application and the device, considering the necessity to ensure the availability of, effective, safe and good quality device relevant to the healthcare needs of the citizens at an affordable price; and

(b) to the NDQAL along with the samples of the device, for evaluation of the quality and the efficacy of the device to which such sample relates.

(5) The Director shall inform Authority and the applicant in writing that the application has been received and submitted to the DEC and the NDQAL.

(6) The Minister may make regulations-

(a) setting out the procedures to be followed by the DEC and the
NDQAL in their respective evaluation process;

(b) specifying-

(i) the time limits to be followed in conducting the evaluation process;

(ii) the manner in which the DEC to conduct its meetings and the procedure to be followed at such meetings; and

(iii) the matters which should be included in the reports to be submitted.

(7) (a) The Authority may direct the DEC and the NDQAL to finalize the evaluation process within a specified time period, where the device is essential for national health.

(b) The DEC and the NDQAL shall within the time limits specified, submit their report on such evaluation to the Director unless there are compelling reasons for any delay.

66. Where all the requirements of the preceding sections of the Act are complied with to the satisfaction of the DR Division and the report of the DEC and NDQAL and the evaluation of the Panel of Experts, if any, have been obtained, the DR Division shall forward to the Authority along with all the prescribed documents, its recommendation in respect of the application.

67. (1) (a) The Authority shall upon taking in to consideration the recommendation submitted by the DR decide whether to register such device or not within one month of the date of receipt of such recommendation.

(b) The Authority may, where necessary call for clarifications from the DEC or any other experts with regard to its report of the DEC and the NDQAL.

(2) The Authority may, where no such clarification is required,
register the device and inform the applicant of such registration in writing, and may inform the public of such registration by order published in the *Gazette*.

(3) (a) The Authority may refuse to grant the registration even where the DR Division recommends the application, in respect of such device for reasons assigned in writing.

(b) Where the Authority refuses to grant a registration in respect of such device, such refusal shall be informed to the applicant within one week of taking such decision.

(4) (a) The Authority shall where it decides to grant registration in respect of any device shall issue a Certificate of Registration to the applicant, who shall, hereinafter in this part, be referred to as “the holder of Certificate”.

(b) The Certificate of Registration shall include the purpose for which the registration is granted, its period of validity and the terms and conditions applicable thereto.

(5) Any registration granted under this section, including device already registered shall be valid for a period mentioned in such Certificate of Registration and may be made subject to such conditions as may be determined by the Authority in accordance with the provisions of this Act.

(6) Upon obtaining the Certificate of registration, the applicant shall enter into an agreement with the Authority to the effect that he shall inform the Authority of any new caution, contraindication or removal of any indication due to new facts within two weeks of such facts been revealed.

68. (1) The holder of certificate may apply to the Authority for renewal of the registration six months prior to the date of expiry of such registration.

(2) The application for such renewal of registration shall be in the prescribed form and shall be accompanied by the prescribed fee.
(3) The Authority shall, upon receiving the application for renewal, submit the application to the DEC for its opinion.

(4) The DEC may, through the Authority, request for samples, documents or any other evidence, which it deems necessary, from the applicant or any other party, for the purpose of evaluation of the device for the renewal of registration.

(5) The Authority may renew the registration for a further period of two years where the Authority is satisfied with the reasons set out in such application for renewal of registration.

69. (1) If the Authority is of the opinion that-

(a) the holder of certificate has failed to comply with any condition subject to which any device has been registered;

(b) the device does not comply with any prescribed requirement;

(c) it is not in the public interest that the device shall be available;

(d) the device has been imported to Sri Lanka before the lapse of one year from the registration of importation;

(e) the holder of Certificate has failed to comply with any direction issued by the Authority; or

(f) the holder of Certificate has violated any provision of the Act or regulation made thereunder,

the Authority shall cause notice of cancellation or suspension to be issued to the holder of the Certificate issued in respect of such device.

(2) Any such notice shall specify the grounds on which the Authority’s opinion is based, and shall indicate that the holder of Certificate may within one month after receipt thereof submit to the
Authority in writing any comments he may wish to forward in respect thereof.

(3) Where the holder of Certificate fails to submit his comments within the time assigned therefor or after consideration of any comments submitted, the Authority is of the opinion that the registration of the device in question shall be suspended or cancelled the Authority shall suspend or cancel the Certificate and inform in writing of such suspension or cancellation to the holder of Certificate immediately.

(4) Where the holder of certificate does not apply for a renewal six months before the expiry date of the certificate, of that particular device shall be deemed to have automatically been cancelled.

PART XI

REGULATION AND CONTROL OF ALL ACTIVITIES RELATING TO COSMETICS

70. (1) No person shall manufacture, prepare, preserve, package, re-pack or store any cosmetic under insanitary conditions.

(2) No person shall import, distribute, re-pack or sell any cosmetic which –

(a) was manufactured, prepared, preserved, packaged or stored 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.
(3) No person shall label, package, treat, process, sell or distribute or advertise any cosmetic in a manner that is false, misleading deceptive or likely to create an erroneous impression regarding its quality, composition, or safety.

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

72. (1) No person shall without prior written approval of the Authority advertise any cosmetic to the public as a treatment, prevention or cure for any of the diseases, disorders, or abnormal physical states as may be prescribed.

(2) No person shall import, sell, or distribute any cosmetic, that is -

(a) represented by a label; or

(b) advertised to the public,

as a treatment prevention or cure for any of the diseases, disorders or abnormal physical states prescribed under subsection (1).

73. No person other than the persons as may be prescribed by regulations shall obtain or have in his possession any prohibited cosmetic which is not safe for general use.

74. (1) There shall be established for the purposes of this Act a Division within the MTSD of the Ministry of Health, to be known as the Cosmetics Regulatory Division (hereinafter referred to as the “the CR Division”).

(2) There shall be a person appointed by the Secretary to be in charge of the CR Division who shall function as a Director under this Act.

(3) The principal function of the CR Division shall be to
coordinate all activities in respect of cosmetics.

(4) The CR Division shall communicate to the Authority through the Head of the CR Division its recommendations in relation to each application for a registration of Cosmetics in Sri Lanka, taking into consideration the evaluation of the Cosmetics Evaluation Committee referred to in section 77.

75. The CR Division shall have under its supervision and control, such number of sub-divisions as may be required for the implementation of its functions relating to registration, quality assurance, regulation of promotion and monitoring of the rational use, determination of a pricing mechanism for cosmetics and the registration of retail outlets, wholesale outlets, distributors and manufacturers of cosmetics.

76. The Secretary may appoint such number of Deputy Directors, Assistant Directors and other officers and advisers as are necessary for the discharge of the functions of the CR Division and they shall be remunerated at such rates as may be determined by the Secretary in consultation with the Secretary to the Ministry of the Minister to whom the subject of Finance is assigned.

77. (1) There shall be appointed for the purposes of this Act a Committee which shall be known the Cosmetics Evaluation Committee (hereinafter referred to as “the CEC”).

(2) The principal function of the CEC shall be to carry out the technical evaluation of the samples of cosmetics submitted with the application for registration and submit a report in respect thereof to the Authority.

(3) The report shall specify the benefits and risks attached to such cosmetics, and the cost effectiveness of such cosmetics in keeping with the national policy.

(4) The CEC shall consist of the following persons who shall be appointed by the Authority, in consultation with the Secretary, -

(a) ex-officio members-
(i) the Director of Medical Technology and Supplies;

(ii) the Director of National Drug Quality Assurance Laboratory;

(iii) the Deputy Director of Medical Technology and Supplies;

(iv) the Deputy Government Analyst;

(v) the Chief Pharmacist of Medical Technology and Supplies;

(vi) the Chief Food and Drug Inspector of Medical Technology and Supplies.

(b) nominated members-

(i) a Professor of Pharmacology of Faculty of Medicine nominated by the Dean of the Faculty;

(ii) a representative of Pharmaceutical Society of Sri Lanka nominated by that Association;

(iii) an Assistant Director of Sri Lanka Standard Institute established under the Sri Lanka Standards Institute Act, No. 6 of 1984 nominated by the Director General of the Sri Lanka Standard Institute;

(iv) a Director of the Consumer Affairs Authority established under the Consumer affairs Authority Act, No. 9 of 2003 nominated by the Chairman of such Authority;

(v) a representative of Ayurveda Teaching Hospital nominated by the Commissioner of Ayurveda;
(vi) a representative of Ayurveda Department of Navinna nominated by the Commissioner of Ayurveda;
(vii) a Pharmacist of Medical Technology and Supplies nominated by the Director of Medical Technology and Supplies;

(5) (a) There shall be appointed a panel of experts from among whom the Director may co-opt additional members to the CEC as and when necessary, depending on the subject matter dealt with by the CEC.

(b) The members who are co-opted shall be present at all meetings for which their presence is required, but they shall have no right to vote thereat.

78. (1) (a) The Authority shall from time to time issue general guidelines to the CEC relating to matters connected with the evaluation of Cosmetics submitted to it and other items which comes within its purview.

(b) These guidelines issued under paragraph (a) may direct the CEC to consider during its process of evaluation, the quality, safety and the cost of each Cosmetic and related item submitted to it.

(2) The CEC shall, based on the general guidelines issued by the Authority, determine the process of evaluation which is to be followed in the evaluation of each cosmetic and related item.

(3) The Minister may make regulations setting out the procedures to be followed, including specified time-limits for the conduct of the evaluation.

79. (1) Any person who wishes to sell, import, manufacture, prepare, store, distribute or promote any cosmetic shall make an application for registration and licensing such cosmetic in the prescribed form, to the CR division.
(2) The application shall be accompanied by the prescribed particulars, the samples of the cosmetic and the prescribed fee.

(3) The Director shall maintain a Register in which every application received for the registration and licensing of a cosmetic shall be recorded. The particulars to be entered in such Register shall be as prescribed.

(4) The Director shall upon receipt of an application submit it together with the sample of the cosmetic and all the other necessary particulars,-

(a) to the CEC, for evaluation of the application and the cosmetic, considering the necessity to ensure the availability of effective, safe and acceptable quality cosmetic; and

(b) to the NDQAL along with the samples of the cosmetic, for evaluation of the quality and the efficacy of the cosmetic to which such samples relates.

(5) The Director shall inform the Authority and the applicant in writing that the application has been received and submitted to the CEC and the NDQAL.

(6) The Minister may make regulations-

(a) setting out the procedure to be followed by the CEC and the NDQAL in their respective evaluation process;

(b) specifying-

(i) the time limits to be followed in the conducting the evaluation process;

(ii) the manner in which the CEC to conduct its meetings and the procedure to be followed at such meetings; and

(iii) the matters which should be included in the reports.
(7) The CEC and NDQAL shall within the time limits prescribed, report to the Director on the progress made in the evaluation process.

80. Where all the requirements of the preceding sections of the Act are complied with to the satisfaction of the CR Division and the report of the CEC and NDQAL and the evaluation of the Panel of Experts, if any, have been obtained, the CR Division shall forward to the Authority along with all the prescribed document, its recommendation in respect of the application.

81. (1) (a) The Authority shall upon taking into consideration the recommendation submitted by the CEC, decide whether to register such cosmetic or not within one month of the date of receipt of such recommendation.

(c) The Authority may, where necessary, call for clarification from the CEC or any other experts with regard to the report of the CEC and NDQAL.

(2) The Authority may where no such clarification is required, register the cosmetic and inform the applicant of the such registration in writing, and may inform the public of such registration by order published in Gazette.

(3) (a) The Authority may refuse to grant registration even where the CR Division recommends the application in respect of such cosmetic for reasons assigned in writing.

(b) Where the Authority refuses to grant a registration in respect of such cosmetic, such refusal shall be informed to the applicant within one week of the date of such decision.

(4) (a) The Authority where it decided to grant the registration in respect of any cosmetic shall issue a Certificate of Registration to the applicant, who shall hereinafter in this Part be referred to as “the holder
of Certificate”.

(b) The Certificate of Registration shall include the purpose for which the registration is granted its period of validity and the terms and conditions applicable thereto.

(5) Any registration granted under this section, including cosmetics already registered shall be valid for a period mentioned in the Certificate of Registration and may be made subject to such conditions as may be determined by the Authority in accordance with the provisions of this Act.

(6) Upon obtaining the Certificate of registration the applicant shall enter into an agreement with the Authority to the effect that he shall inform the Authority of any new side effects, caution, contraindication or removal of any indication due to new facts within two weeks of such facts been revealed.

82. (1) The holder of a certificate may apply to the Authority for renewal of such registration six months prior to the date of expiry of such registration.

(2) The application for such renewal of registration shall be in the prescribed form and shall be accompanied by the prescribed fee.

(3) The Authority shall upon receiving the application, submit the application to the CEC for its opinion.

(4) The CEC may, through the Authority, request for samples, documents or any other evidence, which it deems necessary, from the applicant or any other party, for the purpose of evaluation of the cosmetic for the renewal of registration.

(5) The Authority may renew the registration for a further period of two years where the Authority is satisfied with the reasons set out in the application for the renewal of registration.

83. (1) If the Authority is of the opinion that-
(a) the holder of certificate has failed to comply with any condition subject to which any cosmetic has been registered;

(b) the cosmetic does not comply with any prescribed requirement;

(c) it is not in the public interest that the cosmetic shall be available;

(d) the cosmetic has been imported to Sri Lanka before the lapse of one year from the date of registration of importation;

(e) the holder of Certificate has failed to comply with any direction issued by the Authority; or

(f) the holder of Certificate has violated any provision of the Act or any regulation made thereunder,

the Authority shall cause notice of cancellation or suspension to be issued to the holder of the certificate in respect of such cosmetic.

(2) Any such notice shall specify the grounds on which the Authority’s opinion is based, and shall indicate that the holder of Certificate may within one month after receipt thereof, submit to the Authority in writing any comments he may wish to forward in respect thereof.

(3) Where the holder of Certificate fails to submit his comments within the time assigned therefor or after consideration of any comments submitted, the Authority is of the opinion that the registration of the cosmetic in question shall be suspended or cancelled the Authority shall suspend or cancel the Certificate and inform in writing suspension or cancellation to the holder of Certificate immediately.

(4) Where the holder of Certificate does not apply for a renewal of such certificate six months before its expiry date of the registration of the cosmetic which such Certificate relates shall be deemed to have automatically been cancelled.
84. Any person who is aggrieved by any decision of the Authority made under this Act may appeal to the Appeals Committee appointed in terms of section 85 against such decision.

85. (1) The Minister shall appoint an Appeals Committee to hear appeals made in terms of section 84 of this Act.

(2) The Appeals Committee shall consist of the following –

(a) member appointed from among retired judges of the Supreme Court or the Court of Appeal who shall be the Chairman of the Appeal Committee;

(d) the Secretary; and

(e) a member appointed from among retired Consultant medical officers who has distinguished himself in the field of medicine.

(3) The members of the Appeals Committee shall hold office for a term of three years from the date of appointment, and shall be eligible for reappointment.

(4) The Minister may make regulations specifying the manner in which the meetings and business of the Appeals Committee shall be carried out.

(5) The Appeals Committee may call for opinion of any other individual or any other party which it deemed appropriate, regarding the medicinal drug, device or cosmetic in question.

(6) The Appeals Committee, may after studying the appeal, call for further information regarding the medicinal drug, device or cosmetic in question from the applicant and may call for expert opinion on such medicinal drug, device or cosmetic.

(7) The Appeals Committee shall after studying the appeal, the
further information provided, the reasons for the decision of the Authority and the other evidence, inform its decision to the Authority.

(8) Upon receiving the decision of the Appeals Committee, the Authority shall act in accordance with the decision of the Appeals Committee.

(9) The members of the Appeal Committee may be paid such remuneration out of the Fund of the Authority with the concurrence of the Minister in charge of the subject of finance.

PART XIII

POWERS AND FUNCTION OF THE AUTHORIZED OFFICERS

86. (1) The Minister may appoint-

(a) any Provincial Director of Health Services, any Regional Director of Health Services, any Medical Officer of Health, any Public Health Inspector, any Food and Drugs Inspector or any Pharmacist attached to the Medical Technology and Supply Division; and

(a) any Divisional Pharmacist attached to the Provincial Director of Health Services,

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.

(3) Any Authorized officer who-

(a) acts in contravention of the provisions of this Act or any regulation or rule made thereunder or the provisions of any other written law; or

(b) exercises the powers assigned to him under this Act in a manner or for an intention contrary
to the objects of this Act,

shall, after a due inquiry held by a disciplinary committee appointed by the Minister, be removed from such office.

(4) The Minister shall by regulations, prescribe the constitution of the disciplinary committee and manner of conducting an inquiry.

**87. (1)** An Authorized Officer may, for the performance of his duties and the exercise of his powers –

(a) enter at any reasonable hour to 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 manufacturer, preparation, preservation, packaging or storing of such article;

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

(c) for the purposes of examining or search, stop or detain any vehicles in which he believes that any article is being conveyed, search that vehicle and examine such article and take samples of the said articles;

(d) examine any book, document or other record founds in any place referred to in paragraph (a) and make copies thereof or take extracts therefrom; and

(e) seize and detain for such time as may be necessary any article or vehicle by means of or in relation to which he believes any provisions of this Act or regulations made thereunder have been contravened.
(2) An Authorized Officer acting under this section shall if so required, produce his authority.

(3) 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.

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

(5) Where any Authorized Officer applies to obtain samples of any article exposed for sale, and the person exposing the article 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 (4) to have obstructed an Authorized Officer.

(6) 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.

(7) 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.

(8) 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 Government Institution under the Ministry of Health or under the Provincial Health Services.

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

(10) For the purposes of this section and section 88, “article”
means a medicinal drug, device or cosmetic.

88. (1) Upon the receipt of any information under section 87 (9) where the Authority satisfied that there has not been a contravention of any of the provisions of this Act or any of the regulations made thereunder-

(a) the Authority shall direct the Authorized Officer to release such article and vehicle;

(b) where the owner of such article or the person in possession of such article at the time of seizure-

   (i) consents in writing for the destruction of such article, the Authority shall direct destruction or disposal of such article and release of the vehicle;

   (ii) does not consent in writing to the destruction of such article, the Authority shall direct the Authorized Officer, with notice to such person in possession of the article and owner of such vehicle, to make a complaint to the magistrate’s court having jurisdiction over the area in which the offence was committed of the seizures of the article or vehicle in respect of which the offence was committed.

(2) On complaint being made to the court under subsection (1) (b), such court shall, after trial, if found the owner or person in possession of the article -

(a) 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) 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 thereof.

89. (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 and the part retained by him shall be produced in court at the commencement of the trial 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 of such part of the sample produced in court under subsection (1), to the Approved Analyst.

(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.

90. A copy made or extract taken from any book, document or record by an Authorized Officer under section 87(1) (d) 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.

91. (1) An Authorized Officer may submit any medicinal drug, device or cosmetic seized by him or any portion thereof or any sample taken by him, unless destroyed under section 88(1), to the Approved Analyst for analysis or examination.

(2) Where the Approved Analyst has made an analysis or
examination of the medicinal drugs, devices and cosmetics submitted to him under subsection (1), he shall issue a certificate or report to the Authority and to the relevant authorized officer setting out in that certificate or report the results of his analysis or examination.

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

PART XIV
OFFENCES

92. (1) No person shall store, sell, distribute, re-pack, assemble or transport any illegal, counterfeit or smuggled medicinal drug, device or cosmetic.

(2) No person shall import, sell, distribute, dispense, re-pack, display or store any medicinal drug, device or cosmetic after the expiry date specified on the label, wrapper or container of such medicinal drug, device or cosmetic.

(3) No person shall without lawful authority import, sell, distribute, re-pack, display, assemble or transport any medicinal drug, device or cosmetic containing on its packaging with the state logo or any other mark indicating that such medicinal drug, device or cosmetic are a state property.

(4) Every medicinal drug, device or cosmetic imported in to Sri Lanka shall, possess a seventy five percent (75%) of residual shelf-life at the port of entry.

(5) It shall be the responsibility of the importer to ensure quality, safety and efficacy of every medicinal drug imported by him.

(6) Every person who contravenes any of the provisions of this Act or any regulation made thereunder or fails to comply with any direction given by the Authority 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 two hundred thousand rupees or to imprisonment for a term not exceeding three years or to both such fine and imprisonment;

(b) for unauthorized use of State logo or any other mark which indicates to be State property in relation to medicinal drugs, devices or cosmetics to a fine not exceeding one hundred thousand rupees or to imprisonment for a term not exceeding three years or to both such fine and imprisonment;

(c) for conducting a pharmacy or a drug store without obtaining a licence from the Authority, to a fine not exceeding one hundred thousand rupees or to imprisonment for a term not exceeding three years or to both such fine and imprisonment;

(d) for any other offence –

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

(e) publish an apology in addition to the punishment mentioned in paragraphs (a), (b), (c) and (d) to the general public in two daily newspapers substantially in the size of 10” x 10” in front page in all three languages to the effect that he shall not repeat the offence.

(7) 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 or registration issued to the person convicted for the manufacture, importation, sale and distribution of any medicinal drug, device or cosmetic under this Act or any other law and inform the relevant licensing Authority accordingly.

(8) Where a person convicted of an offence under this Act or the regulations made thereunder relating to the storage, sale, distribution and transportation of any illegal, unregistered, counterfeit, and smuggled medicinal drugs, devices or cosmetics which are marked state logo or any other marking indicating that such medicinal drugs, devices or cosmetics are state property, the Magistrate may, in addition to the punishment provided under this act, upon application made by an Authorized Officer for closure of such premises, order the closure of such premises or discontinuance of trade or business carried on therein.

(9) Where such person fails to comply with the order issued under this section, the Magistrate shall forthwith issue an order to the Fiscal of such Court requiring and authorizing such Fiscal to close such premises and discontinue the trade or business carried on therein before a date specified in the order, not being a date earlier than three days and not later than seven days from the date of issue of such order.

(10) The amount of all fines paid in respect of an offence under this Act or any regulations made thereunder shall be paid and applied as follows:-

(a) (i) sixty percent of the fine to the Authority; and
(ii) fifteen percent of the fine to the Treasury;

(b) it shall be lawful for the court before which an offender is convicted of an offence under this Act to direct in respect of any fine that may be imposed for such offence that a sum not exceeding twenty five—*percentum* of the fine recovered shall be awarded to the Authorized Officer who secures such conviction.

93. 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 Court.

94. (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 proceeding 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-motioned 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.

(4) In any such proceedings the accused may be charged with the
commission of such offence 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.

95. (1) In a prosecution for the offence of sale of any medicinal drug,
device or cosmetic 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 medicinal drug, device or
cosmetic 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 medicinal drug, device
or cosmetic 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 to 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 be purchased the medicinal drug, device or cosmetic and the date of purchase.

Presumptions.

96. (1) For the purposes of this Act and of any regulations made thereunder –

(c) any medicinal drug, device or cosmetic 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;

(d) any substance capable of being used in the composition or preparation of any medicinal drug or cosmetic which is found in premises used in the preparation of medicinal drugs or cosmetic shall be presumed until the contrary is proved, to be intended for use in the composition or preparation of medicinal drugs or cosmetic; and

(e) any offence committed under section 22(6), section 26(1), section 28, section 29, section 54(2) or section 70(3) of this Act shall be presumed until the contrary is proved, to be as an injurious to health of the public.

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

(a) that such medicinal 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 medicinal drug was adulterated by the addition of that other substance.

(3) where a package containing any medicinal drug, device or
cosmetic 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 medicinal drug, device or cosmetic was manufactured or packaged, as the case may be, by the person whose name or address appears on the package.

97. Where an offence under this Act or any regulations made thereunder committed by a body of persons and—

(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 due 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 XV
MISCELLANEOUS

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

(2) The NDQAL and the Medical Research Institute shall be the Additional Approved Analysts.

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

(4) 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 medicinal drugs, devices or cosmetics.

99. (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 analysis or examination 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, upon that party depositing in court the expenses of summoning him including such fees as may be prescribed, payable to him and shall examine him as 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 produce a copy of the report or the certificate and reasonable notice of his intention to produce it.

100. Every Court shall give priority to the trail of any person charged with, or indicted for, any offence under this Act and to the hearing of any appeal from the conviction of any such offence and sentence imposed on such conviction.

101. (1) The provisions of this Act and any regulations made thereunder relating to medicinal drugs which are excisable articles within the meaning of the Excise Ordinance (Chapter 52) shall be in addition to and not in substitution for the provisions of that Ordinance.

(2) The provisions of the Customs Ordinance (Chapter 235) 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 medicinal drug, device or cosmetic.

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

102. (1) Subject to the provisions of this Act the Authority may make rules in respect of all matters for which rules are authorized or required to be made under this Act.

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

103. (1) The Minister may make regulations for the purpose of giving effect to the principles and provisions of this Act or any matter in respect of which regulations are required or authorized to be made under this Act.

(2) Without prejudice to the generality of the powers conferred by subsection (1), the Minister may make regulations in respect of all or any of the following matters:-

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

(b) declaring that any medicinal drug, device or cosmetic is safe for general use or not safe for general use;

(c) the labeling and packaging and the offering, exposing and advertising for sale of medicinal drugs, device, cosmetics or investigational medicinal products;

(d) prescribing the size, dimensions, fill and other specifications of packages of medicinal drugs,
devices, cosmetics or investigational medicinal products;

(e) the use of any substance as an ingredient in any medicinal drug, device or cosmetics 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 purchase;

(f) the standards of composition, strength, potency, purity, quality or other property of medicinal drugs, devices or cosmetics;

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

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

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

(i) requiring persons who manufacture or sell any cosmetic, device, or medicinal drug to furnish information and maintain books and records;

(j) the registration and regulation of pharmacies and drug stores;

(k) the terms and conditions for storage and transport of medicinal drugs, cosmetics or investigational medicinal products;
(l) the disposal of medicinal drugs, devices, cosmetics or investigational medicinal products;

(m) the specification of recalling procedure and composition of committees;

(n) the conditions relating to importers of market authorization holder;

(o) the procedure for parallel imports for non-commercial use by the Government;

(p) the registration, renewal and licensing forms to be used for the purposes of this Act and the regulations made thereunder;

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

(r) prescribing the medicinal drugs, devices or cosmetics prohibited under the Act;

(s) the distribution and the conditions of distribution of sample of any medicinal drug;

(t) the mode and manner in which any medicinal drugs, devices or cosmetics shall be registered, the terms and conditions applicable to such registration and licensing, the fees to be levied for such registration or licensing;

(u) the manner in which the Appeal Committee shall function and procedure of hearing Appeals;

(v) the standards of shelf-life for manufacture of medicinal drugs, devices or cosmetics;

(w) procedure to be followed by the MDEC, DEC and CEC in the conduct of its functions and the transaction of its business;
(x) the procedure of inquiries;

(y) the procedure to be followed by MDEC, DEC and CEC in evaluating process duration and matters which should be included in reports;

(z) the review and revision of manual of Good Manufacturing Practices guidelines (GMP)(Sri Lanka); and

(aa) the procedure for issuing of lot release certificate by Medical Research Institute in relation to vaccines and sera.

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

(4) Every regulation made by the Minister, shall not later than three months after its publication in the Gazette, be brought before Parliament for approval. Any regulation which is not so approved shall be deemed to be rescinded as from the date of such disapproval, but without prejudice to anything previously done thereunder.

(5) A Notification of the date of such disapproval shall be published in the Gazette.

104. The Authority shall be deemed to be a Schedule institution within the meaning of the Bribery Act and the Provisions of that Act, shall be construed accordingly.

105. All members, officers and servants of the Authority shall be deemed to be public servants within the meaning and for the purposes of the Penal Code.

106. (1) 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 or where sample is done, after the expiration of a period of one month from the date of the receipt of Analyst’s report such sample.

107. 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.

PART XVI

REPEALS AND TRANSITIONAL PROVISIONS

108. Cosmetics, Devices and Drugs Act, No. 27 of 1980 is hereby repealed.

109. Notwithstanding the repeal of Cosmetics, Devices and Drugs Act, No. 27 of 1980 (hereinafter referred to as “the repealed Act”, -

(a) the Director –General of Health services, who functioned as the Director –General of Health services of the Cosmetics, Devices and Drugs Authority, by virtue of the provisions of section 20 of the repealed Act, on the day immediately preceding the appointed date shall perform the duties of the Authority, until the Authority commences to perform its duties under this Act;

(b) all contracts, bonds and agreements entered into and are in force on the day immediately preceding the appointed date and all matters and things required to be done by the Cosmetics, Devices and Drugs Authority under the repealed Act, on the day immediately preceding the appointed date shall, with effect from the appointed date be deemed to have
been incurred, executed entered into or engaged to be done by, with or on behalf of the Authority;

(c) all suits, prosecutions, appeals or other legal proceedings which have been instituted in any court or tribunal by or against the Cosmetics, Devices and Drugs Authority and pending before such court or tribunal on the day immediately preceding the appointed date of this Act shall be deemed to have been instituted by or against the Authority and may be continued accordingly;

(d) all decrees, orders and judgments entered, or made by a competent court or tribunal in favor of or against the Cosmetics, Devices and Drugs Authority and remaining unsatisfied on the day immediately preceding the appointed date shall be deemed to have been made in favor of or against the Authority, and may be enforced accordingly;

(e) every regulation or rule made under the repealed Act, and in force on the day immediately preceding the appointed date and not inconsistent with this Act, shall be deemed to have been made under this Act and may accordingly be amended or rescinded by regulations or rules made under this Act;

(f) every licence or registration issued by the Cosmetics, Devices and Drugs Authority and in force immediately prior to the date of operation of this Act shall deemed to be a licence or registration granted by the Authority under the provisions of this Act;

(g) every application for a licence or registration of a prescribed description made to the Cosmetics, Devices and Drugs Authority under the provisions of the repealed Act shall be deemed to be an application made to the Authority established under this Act;

(h) all persons who were members, officers and employee of the Cosmetics, Devices and Drugs Authority on the day
immediately preceding the appointed date, shall, with effect from the appointed date, be deemed to be members, officers and servants of the Authority;

(i) all movable and immovable property vested in the Cosmetics, Devices and Drugs Authority on the day immediately preceding the appointed date, shall, with effect from the appointed date, vested in the Authority;

(j) all sum of money lying to the credit of the fund of the Cosmetics, Devices and Drugs Authority on the day immediately preceding the appointed date, shall stand transferred, with effect from the appointed date, to the Fund established by section 17 of this Act;

(k) all declarations, notifications, licences and orders made or issued under the repealed Act and subsisting on the day immediately preceding the appointed date, shall in so far as they are not inconsistent with the provisions of this Act, be deemed with effect the appointed date, to be declarations, notifications, licences and orders made or issued under the provisions of this Act and shall be construed accordingly;

(l) every reference to the Cosmetics, Devices and Drugs Authority in any written law, notice, notification, instrument, contract, communication or other document shall be read and construed as a reference to the Authority established under this Act; and

(m) every reference to the NDQAL of the Cosmetics, Devices Drugs Authority in any written law, notice, notification, contract, communication or other document shall be read and constructed as a reference to the NDQAL of the Authority established under this Act.

PART XVI
INTERPRETATION
Interpretation.

110. In this Act, unless the context otherwise requires:

“adulterated” means the addition of any substance to or subtraction of any constituent from a medicinal 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, sale or disposal of any medicinal drug, device or cosmetic;

“article” means –

(a) any medicinal drug, device or cosmetic;

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

(c) any labeling or advertising material;

“cosmetic” means 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, perfumes and cosmeceuticals;

“counterfeit cosmetic” means a cosmetic product which is labeled or packaged fraudulently with regard to identification and includes any product with proper ingredients with inferior quality or containing different or inactive ingredients;

“counterfeit device” means a device which is labeled or packaged fraudulently with regard to identification;

“counterfeit medicinal drugs” means a medicinal drug product which
is labeled or packaged fraudulently with regard to identification and includes any product with proper ingredients with inferior quality or containing different or inactive ingredients;

“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, advertised or represented 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, boarder line device/complimentary device but does not include an Ayurvedic device, a Homeopathy device or a medicinal drug;

“Good Manufacturing Practice Guidelines” means guidelines issued by World Health Organization;

“Government Analyst” means the person for the time being holding the office of the Government Analyst, 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 medicinal drug, device or cosmetic with dirt or filth or render same injurious to health or storing medicinal drugs, contrary to the storing instructions given in the label, package or wrapper of the medicinal drug;

“investigational medicinal products” means a product which is under investigation by a clinical trial or equivalent studies which may include a medicinal drug, device or cosmetic;

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

“labeling” includes the label and any written printed or graphic matter relating to and accompanying the medicinal drug, device or cosmetic;

"licence” means a licence issued under this Act;

“Medical Council” means the medical Council established under the section 12 of the Medical Ordinance (Chapter 105);

“medical practitioner” means a person registered as medical practitioner under the Medical Ordinance (Chapter 235);

“medicinal drug” includes –

(a) any substance or mixture of substances manufactured, sold, offered for sale or represented for use in –
(i) the diagnosis, treatment, mitigation or prevention of disease, abnormal physical state or the symptoms thereof in man or animal; and

(ii) restoring, correcting or modifying organic factions in man or animal;

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

(c) a product made out of herbal extract;

(d) neutriceticles;

(e) vaccines and sera,

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

“Minister” means the Minister to whom the subject of Health is assigned and the term Ministry shall be construed accordingly;

“neutriceticle” means a product isolated or purified from food which is generally sold in medicinal form not usually associated with food and provide physiological benefit or protection against chronic disease;

“package” includes anything in which any medicinal drug, cosmetic or device is wholly or partly contained, place or packed;

“person” includes a company;
“Pharmacist” means a Pharmacist registered under the Medical Ordinance (Chapter 105);

“prescribed” means prescribed by rules or regulations made under this Act;

“prescription” means an authorization in writing or otherwise communicated directly to a pharmacist or certified dispenser from a person authorized by law to prescribe medicinal drugs or devices or dispense a specified medicinal drug or device for use by a designated individual or animal;

“prohibited medicinal drug, device or cosmetic” means which are prohibited by regulations made under the Act;

“secretary” means the Secretary to the Minister to whom the subject of Health is assigned;

“sell” means offer, keep or expose for sale, transmit, convey or deliver for sale, for cash or credit or byway of exchange and whether by wholesale or retail and “sale” shall have a corresponding meaning.

“smuggled medicinal drug, device or cosmetic” means a, medicinal drug, device or cosmetic imported or brought in to the country in contravention of the provisions of this Act and without obtaining an import license from the Authority;

“veterinary surgeon” means a person registered as Veterinary Surgeon or a Veterinary Practitioner under the Veterinary Surgeons’ and Practitioner Act. No. 46 of 1956.

111. In the event of an inconsistency between the Sinhala and Tamil texts of this Act, the Sinhala text shall prevail.