# PARLIAMENT OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

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# NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015

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**[Certified on 19th March, 2015]**

*Printed on the Order of Government*

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*National Medicines Regulatory Authority*
*Act, No. 5 of 2015*

[Certified on 19th March, 2015]

L.D.—O. 21/2012

AN ACT TO PROVIDE FOR THE ESTABLISHMENT OF A REGULATORY AUTHORITY TO BE KNOWN AS THE NATIONAL MEDICINES REGULATORY AUTHORITY WHICH SHALL BE RESPONSIBLE FOR THE REGULATION AND CONTROL OF, REGISTRATION, LICENSING, MANUFACTURE, IMPORTATION AND ALL OTHER ASPECTS PERTAINING TO MEDICINES, MEDICAL DEVICES, BOARDERLINE PRODUCTS AND FOR THE CONDUCTING OF CLINICAL TRIALS IN A MANNER COMPATIBLE WITH THE NATIONAL MEDICINES POLICY; TO PROVIDE FOR THE ESTABLISHMENT OF DIVISIONS OF THE NATIONAL MEDICINES REGULATORY AUTHORITY INCLUDING THE MEDICINES REGULATORY DIVISION, MEDICAL DEVICES REGULATORY DIVISION, BORDERLINE PRODUCTS REGULATORY DIVISION AND CLINICAL TRIALS REGULATORY DIVISION; TO ESTABLISH A NATIONAL ADVISORY BODY; 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 :-

Short title and date of operation.

**1.** This Act may be cited as the National Medicines Regulatory Authority Act, No. 5 of 2015 and 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").

2—PL 008818—2,950 (02/2015)

CHAPTER I

## NATIONAL MEDICINES REGULATORY AUTHORITY

PART I

ESTABLISHMENT OF THE AUTHORITY

Establishment of the National Medicines Regulatory Authority.

**2.** (1) There shall be established an authority called the National Medicines Regulatory Authority (hereinafter referred to as the 'Authority').

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

Objects of the Authority.

**3.** The objects of the Authority shall be to –

(*a*) ensure the availability of efficacious, safe and good quality medicines, efficacious, safe and good quality medical devices and efficacious, safe and good quality borderline products to the general public at affordable prices;

(*b*) function as the central regulator for all matters connected with the registration, licensing, cancellation of registration or licensing, pricing, manufacture, importation, storage, transport, distribution, sale, advertising and disposal of medicines, medical devices and borderline products;

(*c*) ensure that all activities related to registration, licensing and importation of medicines, medical devices, borderline products and investigational medicinal products are carried out in a transparent, sustainable and equitable manner;

(*d*) encourage the manufacturing of good quality medicines in Sri Lanka with a view to assuring the availability of essential medicines at affordable prices;

(*e*) promote the safe and rational use of medicines, medical devices and borderline products by health care professionals and consumers;

(*f*) recommend appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products;

(*g*) educate the general public, health care professionals and all stakeholders on medicines, medical devices and borderline products;

(*h*) regulate the promotion and marketing of medicines, medical devices and borderline products;

(*i*) regulate the availability of the medicines, medical devices and borderline products;

(*j*) conduct post marketing surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products; and

(*k*) regulate all matters pertaining to the conduct of clinical trials in Sri Lanka.

Constitution of the Authority.

**4.** The Authority shall consist of the following :-

(*a*) *ex-officio* members –

(i) the Director-General of Health Services;

(ii) the Secretary to the Treasury or his nominee; and

(iii) the Chief Executive Officer of the Authority appointed under section 15 who shall function as the Secretary to the Authority;

(*b*) following persons who shall be appointed by the Minister, (hereinafter referred to as "appointed members") –

(i) four 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) Pediatrics; and

(D) Gynaecology and Obstetrics;

(ii) a Professor in Pharmacology of any University in Sri Lanka established under the Universities Act, No.16 of 1978, appointed in rotation for every three years, in consultation with the respective Deans of Faculties of Medicine;

(iii) a Professor or Senior Lecturer in Pharmacy of any University in Sri Lanka established under the Universities Act, No.16 of 1978, appointed in rotation for every three years, in consultation with the respective Deans of relevant Faculties;

(iv) four professionals, who have gained eminence in the fields of management, law, accountancy or health respectively.

Chairman of the Authority.

**5.** (1) The Minister shall, in consultation with the Authority appoint one of the appointed members to be the Chairman of the Authority.

(2) The Chairman may resign from the office of Chairman by letter addressed to the Minister and such resignation shall be effective from the date on which it is accepted by the Minister.

(3) The Minister may for reasons assigned remove the Chairman from the office of Chairman.

(4) Subject to the provisions of subsections (2) and (3), the term of office of the Chairman shall be the period of his membership of the Authority.

(5) Where the Chairman is temporarily unable to perform the duties of his office due to ill health, other infirmity, absence from Sri Lanka or any other cause, the Minister may appoint any other appointed member to act as Chairman in addition to his normal duties as an appointed member.

Conflict of interests of the members.

**6.** (1) The Minister shall, prior to appointing a person as a member of the Authority, satisfy himself that such person has no financial or other conflict of interest in the affairs of the Authority, as is likely to affect adversely, the discharging of his functions as a member of the Authority.

(2) The Minister shall also satisfy himself, from time to time, that no member of the Authority has since being appointed acquired any such interest.

(3) The person to be appointed as a member of the Authority shall be a person who has not been engaged in any employment or assignment in the pharmaceutical industry within the period of three years immediately prior to such appointment.

(4) No person shall engage in any employment or assisgnment in the pharmaceutical industry within the period of three years immediately after such person ceased to be a member of the Authority.

(5) (*a*) A member of the Authority who is in any way, directly or indirectly interested in any contract made or

proposed to be made by the Authority shall disclose the nature of his interest at a meeting of the Authority; and

(*b*) Such disclosure shall be recorded in the minutes of the Authority and the member shall not participate in any deliberation or decision of the Authority with regard to that contract.

(6) Minister may make regulations to further specify and give effect to the provisions of this section.

(7) For the purposes of this section-

"a member of the Authority" includes the Chairman, an appointed member and an *ex-officio* member; and

"conflict of interest" includes any dealing with any company or undertaking which engages in manufacturing, importation, distribution or sale of medicines, medical devices, borderline products or investigational medicinal products.

Disqualifications to be a member.

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

(*a*) is or becomes a Member of Parliament, any Provincial Council or of any Local Authority;

(*b*) is not, or ceases to be, a citizen of Sri Lanka;

(*c*) directly or indirectly holds or enjoys any right or benefit under any contract made by or on behalf of the Authority;

(*d*) has any financial or other interest as is likely to affect prejudicially the discharge by him of his functions as a member of the Authority;

(*e*) is absent himself from three consecutive meetings of the Authority;

(*f*) is under any law in force in Sri Lanka or any other country, found or declared to be of unsound mind;

(g) is a person who having been declared as insolvent or bankrupt under any law in force in Sri Lanka or in any other country, is an undischarged insolvent or bankrupt; or

(*h*) is serving or has served a sentence of imprisonment imposed by any court in Sri Lanka or any other country.

*Ex-officio* members.

**8.** Every *ex-officio* member of the Authority shall hold office so long as such officer holds office by virtue of which such officer has been appointed to the Authority.

Provisions relating to appointed members.

**9.** (1) Every appointed member of the Authority shall, unless such officer vacates office earlier by death, resignation or removal, hold office for a period of three years, and shall be eligible for re-appointment, unless removed on disciplinary grounds.

(2) The Minister may for reasons assigned remove any appointed member from office.

(3) Any appointed member may resign from office at any time by letter addressed in that behalf to the Minister and such resignation shall take effect upon it being accepted by the Minister.

(4) (*a*) In the event of the death, resignation or removal from office of any appointed member, the Minister may having regard to the provisions of this Act in relation to the appointment of that particular appointed member, appoint another person to act in his place.

(*b*) The Minister shall appoint the member for the purposes of paragraph (*a*) within one month of the occurrence of such vacancy.

(*c*) The member appointed under paragraph (*a*) shall hold office for the unexpired period of the term of office of the member whom he succeeds.

(5) Where any appointed member is temporarily unable to perform the duties of his office due to ill health or absence from Sri Lanka or for any other reason, the Minister may having regard to the provisions of section 4(*b*) appoint another person to act in his place.

(6) Subject to the preceding provisions, an appointed member may continue to hold office, after lapse of the period of three years referred to in subsection (1), until he is reappointed or a new member is appointed by the Minister.

Meetings of the Authority.

**10.** (1) The Chairman shall preside at every meeting of the Authority. Where the Chairman is absent, the members present shall elect a Chairman for that meeting from among themselves.

(2) (*a*) All matters for decision by the Authority shall be dealt with at a meeting, of the Authority and shall be determined by the majority of the members present and voting.

(*b*) In the event of an equality of votes on any question considered at a meeting the Chairman of that meeting shall have a casting vote in addition to his original vote.

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

(3) (*a*) Any member of the Authority may by written notice, request the Chairman to call a meeting and the Chairman shall not otherwise than for justifiable reasons refuse to do so.

(*b*) The Chief Executive Officer appointed under section 15 shall summon all meetings of the Authority.

(4) No act, decision or proceeding of the Authority, shall be deemed to be invalidated by reason only of the existence of any vacancy of the Authority or any defect in the appointment of any member thereof.

(5) The quorum for any meeting of the Authority shall be seven.

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

The Seal.

**11.** (1) The seal of the Authority shall be as determined by the Authority.

(2) The seal of the Authority -

(*a*) may be altered in such manner as may be determined by the Authority;

(*b*) shall be in the custody of such person or persons as the Authority may, determine;

(*c*) shall not be affixed to any instrument or document without the sanction of the Authority and except in the presence of two members of the Authority, both of whom shall sign the instrument or document in token of their presence.

(3) The Authority shall maintain a register of documents to which the seal of the Authority has been affixed.

Authority to invite experts to meetings.

**12.** (*a*) The Authority may invite experts on a relevant subject matter to meetings of the Authority for the purpose of obtaining their views for the effective discharge of the functions of the Authority.

(*b*) The Authority shall have the discretion of accepting or rejecting the views of the experts.

(*c*) The experts shall have no voting rights.

Remuneration for attending meetings of the Authority.

**13.** The members of the Authority and the experts may be paid such remuneration for attendance at meetings of the Authority, as may be determined by the Minister with the concurrence of the Minister assigned the subject of Finance.

Powers and functions of theAuthority.

**14.** The powers and functions of the Authority shall be to :-

(*a*) decide on classifying a product as a medicine, medical device, borderline product or any other product;

(*b*) authorize registration and licensing of medicines, medical devices, borderline products and investigational medicinal products or cancel or suspend any such registration or licence in terms of this Act;

(*c*) regulate the registration, licensing, manufacture, importation, storage, re-packing, transportation, distribution, sale, advertising, promotion, recall and disposal of medicines, medical devices, borderline products or investigational medicinal products;

(*d*) authorize registration and regulation of Pharmacies and medicines stores;

(*e*) issue licences for manufacture, import, storage, distribution, transport and sale of medicines, medical devices, borderline products or investigational medicinal products and to cancel such licences in terms of this Act;

(*f*) appoint sub-committees as may be necessary for the effective discharge of the functions of the Authority;

(*g*) grant approval for the custom clearance of consignments of medicines, medical devices, borderline products, raw materials, packing materials, machinery or laboratory material needed for local manufacture of medicines, medical devices, borderline products or investigational medicinal products subject to the provisions of this Act and any other written law;

(*h*) conduct awareness programmes in relation to medicines, medical devices and borderline products and post market surveillance on the quality and safety of medicines, medical devices, borderline products and investigational medicinal products which are registered and licensed under this Act;

(*i*) monitor the registration and licensing process and the usage of medicines, medical devices, borderline products 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;

(*j*) collect data on quantities of medicines, medical devices, borderline products or investigational medicinal products imported under licences;

(*k*) collect data on utilization of medicines, medical devices, borderline products and investigational medicinal products in Sri Lanka, including data on expenditure of industry and trade, relating to promotional activities;

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

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

(*n*) charge fees where necessary and appropriate in the discharge of its functions;

(*o*) recognize and appoint other local or overseas laboratories for testing of any medicine, medical device or borderline product as may be deemed necessary;

(*p*) follow Good Regulatory Practices (GRP) as prescribed in regulations;

(*q*) determine the initial price of medicines, medical devices and borderline products and advise the Minister on subsequent price revisions;

(*r*) provide information pertaining to the functions of the Authority to the stakeholders and general public; and

(*s*) issue, review and update guidelines, recommendations, directives and rules as applicable to medicines, medical devices and borderline products.

## PART II

### APPOINTMENT OF CHIEF EXECUTIVE OFFICER AND STAFF OF THE AUTHORITY

Appointment of the Chief Executive Officer of the Authority.

**15.** (1) The Authority shall in consultation with the Minister, appoint to the Staff of the Authority a Chief Executive Officer (hereinafter referred to as the "CEO") from among persons who hold a postgraduate degree from a recognized University in Medicine, Pharmacology, Pharmacy or any other related discipline with at least five years management experience at senior executive level.

(2) The CEO shall subject to the general directions and supervision of the Authority -

(*a*) be charged with the administration of the affairs of the Authority including the administration and control of the staff;

(*b*) be responsible for the execution of all decisions of the Authority;

(*c*) carry out all such functions as may be assigned to him by the Authority; and

(*d*) function as the Secretary to the Authority.

(3) The Authority may in consultation with the Minister remove the CEO from office -

(*a*) if he becomes permanently incapable of performing his duties;

(*b*) if he has done any act which, is of a fraudulent or illegal character or is prejudicial to the interests of the Authority; or

(*c*) has failed to comply with any directions issued by the Authority.

(4) The term of office of the CEO shall be for a period of three years from the date of appointment and shall be eligible for re-appointment.

(5) The office of the CEO shall become vacant upon the death, removal from office under subsection (3) or resignation by letter in that behalf addressed to the Minister by the holder of that office.

(6) If any vacancy occurs in the office of the CEO, the Authority may appoint any other suitable officer of the Authority to perform the duties of the CEO until an appointment is made under subsection (1).

Staff of the Authority.

**16.** (1) The Authority may appoint such technical and other officers and employees as may be necessary for the efficient discharge of its functions.

(2) The Authority may, in respect of the officers and employees appointed to the Authority under subsection (1)-

(*a*) exercise disciplinary control over or dismiss such officers and employees;

(*b*) fix the rates at which such officers and employees shall be remunerated in keeping with related guidelines of the Government;

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

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

(3) The Authority may make rules in respect of all or any of the matters referred to in subsections (1) and (2).

(4) The Authority shall not however appoint as an officer or an employee of the Authority, any person who has been dismissed from any previous position held by such person in the public or private sector as an officer or an employee.

Public officers to be appointed to the Staff of the Authority.

**17.** (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 under which that officer is employed, and the Secretary to the Ministry of the Minister assigned 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 any officer or employee of the Department of Health is appointed to the staff of the Authority, the provisions of sections 16, 17, 18 and 19 of the National Aquaculture Development Authority of Sri Lanka Act, No. 53 of 1998 shall *mutatis mutandis* apply to and in relation to such officer or employee.

(5) Where the Authority employs any person who has entered into a contract with the Government by which he

has agreed to serve the Government for a specified period, any period of service with the Authority by that person shall be regarded as service to the Government for the purpose of discharging the obligations of such contract.

## PART III

### FINANCE

Fund of the Authority.

**18.** (1) The Authority shall have its own Fund.

(2) There shall be paid into the Fund -

(*a*) all such sums of money as may be voted upon 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 charges and levied for services provided by the Authority under this Act;

(*c*) all such sums of money as may be received by the Authority in the exercise, performance and discharge of its powers and functions under this Act;

(*d*) all such sums of money as may be received by the Authority by way of loans, donations, gifts and grants ;

(*e*) all such sums of money accruing to the credit of the Authority; and

(*f*) all such sums of money received by alienating, leasing or renting of property owned by the Authority.

(3) There shall be paid out of the Fund all such sums of money required to defray the expenditure incurred by the Authority in the exercise and performance of its powers and functions under this Act.

Authority to maintain accounts.

**19.** The Authority may open and maintain any account with any bank as it may think appropriate, and such account shall be operated in accordance with prevailing financial regulations of the Government pertaining to financial transactions of public corporations.

Financial year and audit of accounts.

**20.** (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 the income and expenditure, assets and liabilities and all other financial transactions of the Authority.

(3) For the purpose of presenting a true and fair view of the financial performance and financial condition of the Authority, the Authority shall prepare the accounts in accordance with the Sri Lanka Accounting Standards adopted by the Institute of Chartered Accountants of Sri Lanka under the Sri Lanka Accounting and Auditing Standards Act, No. 15 of 1995.

(4) The provisions of Article 154 of the Constitution relating to the audit of accounts of public corporations shall apply to the audit of the accounts of the Authority.

Investment of funds.

**21.** Moneys belonging to the Authority may, with the approval of the Minister and with the concurrence of the Minister assigned the subject of Finance, be invested in Government approved securities.

Borrowing powers of the Authority.

**22.** (1) The Authority may, with the written consent of the Minister and the Minister assigned the subject of Finance and in accordance with the terms of any general authority given, borrow or obtain on credit terms such sums as the Authority may require to meet the obligations of the Authority.

(2) The aggregate of the amount outstanding in respect of any loans raised by the Authority under this section shall not at any time exceed such amount as may be determined by the Minister.

## PART IV

### GENERAL

Annual Report.

**23.** (1) The Authority shall within six months of the end of each financial year, submit to the Minister an annual report of the activities carried on by the Authority during that financial year, and cause a copy each of the following documents to be attached to the report –

(*a*) the audited accounts of the Authority for the year along with the Auditor-General's report; and

(*b*) a report of proposed activities for the year immediately following, the year to which such report and accounts relates.

(2) The Minister shall lay copies of the report and documents submitted under subsection (1) before Parliament within six months from the date of receipt of such report.

Declaration of secrecy.

**24.** Every member of the Authority and all officers and employees of the Authority shall, before entering upon duties, sign a declaration pledging to observe strict secrecy in respect of all matters connected with the affairs of the Authority, which has come to his knowledge in the performance or exercise of his powers and functions under this Act and shall by such declaration pledge himself not to disclose any such matter, except -

(*a*) when required to do so by a court of law; or

(*b*) for the purpose of exercising or performing the powers and functions under this Act or any other written law.

Delegation of powers of the Authority.

**25.** (1) The Authority may in writing and subject to such conditions as may be specified therein, delegate to the CEO and any Head of the relevant division of the Authority any of its powers or functions and any such person or any Head of the relevant division shall exercise or perform such powers or functions in the name and on behalf, of the Authority.

(2) The Authority may, notwithstanding any delegation made under subsection (1), by itself exercise or perform any power or function so delegated and may at any time revoke any such delegation.

Directions by the Minister.

**26.** (1) The Minister may from time to time, issue to the Authority such general or special directions in writing as to the exercise and performance of its powers and functions so as to ensure the giving proper effect to Government Policy and it shall be the duty of the Authority to give effect to such directions.

(2) The Minister may direct the Authority to furnish to him in such form as he may require, returns, accounts and any other information relating to the work of the Authority, and it shall be the duty of the Authority to give effect to such directions.

Officers and employees of the Authority deemed to be public officers.

**27.** The CEO and the officers and employees of the Authority shall be deemed to be public officers within the meaning of and for the purposes of the Penal Code .

Authority deemed to be a Scheduled institution.

**28.** The Authority shall be deemed to be a Scheduled Institution within the meaning and for the purposes of the Bribery Act and the provisions of that Act shall be construed accordingly.

Expenses in suit or prosecution to be paid out of the Fund.

**29.** (1) Any expenses incurred by the Authority in any suit or prosecution brought by or against it before any Court, shall be paid out of the Fund of the Authority and any costs paid to or recovered by the Authority in any such suit or prosecution shall be credited to the Fund of the Authority.

(2) Expenses incurred by any member, the CEO or any officer or employee of the Authority in any suit or prosecution brought against him before any Court or Tribunal in respect of any act which is done or purported to be done by him under the provisions of this Act or any other written law or if the court holds that such act was done in good faith, be paid out of the Fund of the Authority, unless such expenses are recoverable by him in such suit or prosecution.

## CHAPTER II

## NATIONAL ADVISORY COMMITTEE AND DIVISIONS OF THE AUTHORITY

### PART I

### ESTABLISHMENT OF NATIONAL ADVISORY COMMITTEE AND DIVISIONS

Establishment of National Advisory Committee and divisions.

**30.** (1) There shall be established a National Advisory Committee, the main function of which shall be to advise the Minister and the Authority on matters pertaining to proper implementation of the National Medicines Policy of Sri Lanka.

(2) There shall be established divisions of the Authority including the following divisions-

(i) National Medicine Quality Assurance Laboratory (NMQAL) which shall be responsible for the analysing of the quality of any medicine, medical device or borderline product forwarded by the Authority.

(ii) Medicines Regulatory Division, which shall be responsible for regulation and control of all aspects pertaining to medicines as may be authorized and directed by the Authority;

(iii) Medical Devices Regulatory Division which shall be responsible for regulation and control of all aspects pertaining to medical devices as may be authorized and directed by the Authority;

(iv) Borderline Products Regulatory Division which shall be responsible for regulation and control of all aspects pertaining to borderline products as may be authorized and directed by the Authority;

(v) Clinical Trials Regulatory Division which shall be responsible for regulation and control of all aspects pertaining to clinical trials carried out in Sri Lanka as may be authorized and directed by the Authority;

(vi) Information, Education, Communication and Research Division which shall be responsible for educating the people as well as stake holders and healthcare professionals on rational use of medicines, medical devices and borderline products and promoting research into medicines, medical devices and borderline products as may be authorized and directed by the Authority;

(vii) Inspectorate and Enforcement Division which shall be responsible for inspecting and investigating issues pertaining to proper implementation of the provisions of this Act as may be authorized and directed by the Authority;

(viii) Pharmacovigilance Division which shall be responsible for monitoring and dealing with adverse drug reaction, quality failure and counterteit medicines as may be authorized and directed by the Authority;

(ix) Pharmacies Regulatory Division which shall be responsible for the regulation and control of pharmacies in Sri Lanka as may be authorized and directed by the Authority;

(x) Manufacturing Regulatory Division which shall be responsible for the regulation and promotion of manufacturing of good quality medicines, medical devices and borderline products in Sri Lanka; and

(xi) Organization Development Division which shall be responsible for the Human Resources, Finance, Administration and Audit of the Authority as may be authorized and directed by the Authority.

(3) The Authority shall appoint a head to each division who shall communicate with the Authority on behalf of such division.

(4) The Authority may where necessary-

(*a*) establish any other division or sub division;

(*b*) merge any two or more divisions or discontinue any division or subdivision.

(5) The Authority shall appoint such number of officers, employees and advisors as may be necessary for the proper discharge of the functions of a division or a sub division.

(6) All rules and regulations applicable for the Staff of the Authority referred to in sections 16 and 17 of this Act shall be applicable to the officers, advisors and employees of any division or sub division.

## PART II

### NATIONAL ADVISORY COMMITTEE

Constitution of the National Advisory Committee.

**31.** (1) The National Advisory Committee shall consist of the following members appointed by the Minister -

(*a*) the Director General of Health Services;

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

(*c*) the Chairman of the Authority;

(*d*) a nominee from the Secretary to the Treasury;

(*e*) the Chairman of the State Pharmaceuticals Corporation of Sri Lanka established under State Industrial Corporation Act, No. 49 of 1957;

(*f*) a Professor in Pharmacology in any University in Sri Lanka established under the Universities Act, No. 16 of 1978, appointed in consultation with the respective Deans of the relevant Medical Faculties;

(*g*) a Pharmacologist from the Ministry of Health nominated by the Director General of Health Services;

(*h*) the President of the Sri Lanka Medical Association or his nominee;

(*i*) the President of the Pharmaceutical Society of Sri Lanka or his nominee;

(*j*) the Commissioner of Ayurveda or his nominee;

(*k*) Director General of Customs or his nominee;

(*l*) a legal officer from the Ministry of Health nominated by the Secretary;

(*m*) a representative of the Ceylon College of Physicians nominated by that College;

(*n*) a representative of the College of Surgeons of Sri Lanka nominated by that College;

(*o*) a representative of the College of General Practitioners of Sri Lanka nominated by that College;

(*p*) a representative of the College of Community Physicians of Sri Lanka nominated by that College;

(*q*) a representative from the Attorney General's Department nominated by the Attorney General;

(*r*) a representative from the Consumer Affairs Authority nominated by the Chairman of that Authority;

(*s*) a representative of the Sri Lanka Standards Institution established under the Sri Lanka Standards Institution Act, No. 6 of 1984, nominated by the Director General of such Institution;

(*t*) a representative from a patient interest group nominated by the Minister of Health;

(*u*) a representative from the Sri Lanka Pharmaceutical Manufacturers Association nominated by that Association;

(*v*) a representative from the Sri Lanka Chamber of the Pharmaceutical Industry nominated by such Chamber;

(*w*) a representative of the public nominated by the Minister; and

(*x*) a representative of the Senaka Bibile Commemoration Committee.

(2) (*a*) Every member of the National Advisory Committee 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.

(*b*) Every other member of the National Advisory Committee shall hold office so long as such member holds office by virtue of which such member has been appointed to the National Advisory Committee.

Chairman &c., of the National Advisory Committee.

**32.** (1) The Minister shall appoint any member of the National Advisory Committee as the Chairman of the National Advisory Committee.

(2) The National Advisory Committee may discharge its functions notwithstanding any vacancy among its membership.

(3) The quorum for any meeting of the National Advisory Committee shall be eleven members.

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

Remuneration of the members of the National Advisory Committee.

**33.** The members of the National Advisory Committee, shall not receive any remuneration for being in the National Advisory Committee, except an honorarium which may be given for attending at the meetings of the National Advisory Committee.

Appointment of officers, employees &c.

**34.** (*a*) The Authority shall appoint such number of officers employees and advisors as may be necessary for the proper discharge of the functions of the National Advisory Committee.

(*b*) All rules and regulations applicable for the staff of the Authority referred to in sections 16 and 17 of this Act shall be applicable to the officers, employees and advisers referred to paragraph (*a*).

Functions of the National Advisory Committee.

**35.** The functions of the National Advisory Committee shall be -

(*a*) the overall supervision of the proper implementation of the provisions of this Act;

(*b*) the overall supervision of the proper implementation of the national medicines policy; and

(*c*) to advise the Minister and the Authority on issues pertaining to the matters specified in paragraphs (*a*) and (*b*) and any other related matters.

Regulations.

**36.** The Minister may make regulations to give effect to the provisions of this Part of this Act.

Application of certain provisions of this Act in relation to National Advisory Committee.

**37.** The provisions of sections 5, 6, 7, 8, 9, 10, 11, 12 and 13 of this Act shall *mutatis mutandis* apply to and in relation to the Chairman, members and the conducting of the affairs of the National Advisory Committee.

## PART III

### National Medicines Quality Assurance Laboratory

Establishment of the National Medicines Quality Assurance Laboratory.

**38.** (1) For the purpose of this Act there shall be a Division to be known as the National Medicines Quality Assurance Laboratory (hereinafter referred to as the "NMQAL").

(2) (*a*) The National Drug Quality Assurance Laboratory functioning under the Ministry of the Minister on the day immediately preceding the appointed date shall, with effect from the appointed date, be vested with the Authority and shall be deemed to be the NMQAL for the purposes of this Act.

(*b*) All testing assignments and other work assigned to the National Drug Quality Assurance Laboratory and pending on the appointed date, shall, with effect from the appointed date, be carried out and completed by the NMQAL.

(*c*) Any officer or employee of the National Drug Quality Assurance Laboratory may, with effect from the appointed date, be employed in the NMQAL and the provisions of sections 16, 17, 18 and 19 of the National Aquaculture Development Authority of Sri Lanka Act, No. 53 of 1998 shall *mutatis mutandis* apply to and in relation to such officer or employee.

Functions of NMQAL.

**39.** (1) The functions of the NMQAL shall be -

(*a*) the testing of the quality of medicines, medical devices or borderline products submitted by the Authority 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 the Authority;

(v) submitted by the Authority for any reason other than the reasons specified above;

(*b*) to function, as an additional approved Analyst, when the circumstances so require;

(*c*) to coordinate with laboratories local or overseas when their services are deemed necessary as decided by the Authority;

(*d*) to carry out research projects pertaining to quality assurance of medicines, medical devices or borderline products.

(2) The NMQAL shall carry out any other functions as may be requested by the Authority and the Department of Health through the Authority.

(3) The NMQAL shall carry out any testing or analysis of an article submitted to the NMQAL strictly according to the quality and standards guidelines as may be introduced by the Authority, from time to time.

(4) The NMQAL shall submit the analysis report on the quality and standards of the article submitted within the time period stipulated by the Authority.

(5) For the purposes of this part of this Act "article" includes any article of medicine, medical device, borderline product or investigational medicinal product.

Regulations.

**40.** The Minister may make regulations to give effect to the provisions of this Part of this Act.

## CHAPTER III

## REGULATION AND CONTROL OF ALL ASPECTS PERTAINING TO MEDICINES

### PART I

### MEDICINES REGULATORY DIVISION

Medicines Regulatory Division.

**41.** (1) The Medicines Regulatory Division established under section 30(2) shall hereinafter in this Act be referred to as the MR Division.

(2) The Authority shall appoint the head of the MR Division from among persons holding a recognized degree in Medicine, Pharmacology, Pharmacy or any other related discipline.

Functions of the MR Division.

**42.** (*a*) The principal function of the MR Division shall be to co-ordinate and assist the Authority to regulate and control all aspects pertaining to medicines.

(*b*) The other functions of the MR Division shall be the -

(i) co-ordination of applications submitted for registration of medicines and renewal of such registration;

(ii) co-ordination of matters pertaining to cancellation or suspension of registration of medicines;

(iii) co-ordination of matters pertaining to registration of importers and distributers of medicines;

(iv) co-ordination of the issuance of licences under this section; and

(v) provisions of administrative assistance to the Medicines Evaluation Committee appointed under section 43 of this Act.

PART II

MEDICINES EVALUATION

Medicines Evaluation Committee.

**43.** (1) There shall be appointed for the purposes of this Act, a Committee which shall be known as the Medicines Evaluation Committee (hereinafter referred to as "the MEC").

(2) (*a*)The principal function of the MEC shall be to carry out the technical evaluation of the medicines forwarded for registration and submit a report in respect thereof to the Authority.

(*b*) The report shall specify the benefits and risks attached to such medicines and the quality, efficacy, safety, need and cost of such medicines with pharmacoeconomic analysis where necessary in keeping with the National Medicines Policy.

Constitution of the MEC.

**44.** (1) The MEC shall consist of the following persons who shall be appointed by the Authority -

*(a)* *ex officio* members –

(i) the head of the MR Division who shall function as the Chairman of the Committee;

(ii) the head of the National Medicines Quality Assurance Laboratory (NMQAL);

(*b*) nominated members -

(i) four specialist clinicians attached to the Ministry of Health representing the following fields, nominated by their respective professional bodies-

(A) General Medicine;

(B) General Surgery;

(C) Pediatrics; and

(D) Gynaecology and Obstetrics;

(ii) a Professor in Pharmacology in University of Colombo established under the Universities Act, No. 16 of 1978, nominated by the Dean of the Faculty of Medicine;

(iii) a Professor or Senior Lecturer in Pharmacy of any University established under the Universities Act, No.16 of 1978, nominated by the Deans of relevant Faculties; and

(iv) a Pharmacist functioning under the Authority.

(2) The quorum for meetings shall be five members excluding the members of the Panel of Experts.

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

Panel of Experts.

**45.** (1) The Authority shall appoint a Panel of Experts, comprising of eminent professionals of medicine and other relevant fields.

(2) The Authority may where necessary appoint additional members to the MEC from the Panel of Experts, depending on the subject matter dealt with by the MEC.

(3) The members appointed under subsection (2) shall be present at the meetings for which their presence is required and express their opinion but they shall have no voting rights at such meetings.

Declaration of secrecy.

**46.** Every member of the MR Division and the MEC and all officers and employees of the MR Division and the MEC shall, before entering upon duties, sign a declaration pledging to observe strict secrecy in respect of all matters connected with the affairs of the MR Division and the MEC, which has come to his knowledge in the performance or exercise of his powers and functions under this Act and shall by such declaration pledge himself not to disclose any such matter, except -

(*a*) when required to do so by a court of law; or

(*b*) for the purpose of exercising or performing the powers and functions under this Act or any other written law.

Authority to give general guidelines for the evaluation.

**47.** (1) The Authority shall issue general guidelines to the MEC for the evaluation of medicines and other related items, submitted to the MEC.

(2) (*a*) The general guide lines referred to in subsection (1) shall be based on the Good Manufacturing Practices (GMP) and other recommendations issued by the World Health Organization and other regulatory bodies recognized by the Authority.

(*b*) The Authority may revise the general guidelines from time to time in order to maintain parallels with internationally recognized standards and practices.

(3) The MEC shall take into consideration the efficacy, safety, quality, need and cost of each medicine, in the process of evaluation and may consider pharmacoeconomic analysis where necessary.

(4) The Minister may make regulations -

(*a*) setting out the procedures to be followed, including the specified time limits, for the conduct of respective evaluations;

(*b*) to give effect to the Good Manufacturing Practices (GMP) guidelines, Good Review Practices (GRP) and any other applicable guidelines as may be recommended by the Authority; and

(*c*) in respect of bioequivalence and biowaiver data relating to generic medicines submitted for evaluation.

Application of certain provisions of this Act in relation to MEC.

**48.** The provisions of sections 5, 6, 7, 8, 9, 10, 11, 12 and 13 of this Act shall *mutatis mutandis* apply to and in respect of the Chairman, members and the conducting of the affairs of the MEC.

## PART III

### OFFENCES PERTAINING TO MEDICINE

Regulation of manufacture, importation, sale and distribution of medicine.

**49.** (1) No person shall import, distribute, exhibit or sell any medicine that-

(*a*) is manufactured, prepared, preserved, packaged or stored under insanitary conditions;

(*b*) consists in whole or in part any contaminant or decomposed substance or any foreign matter;

(*c*) has in or upon it any deleterious substance that may cause injury to the health of the user; or

(*d*) is adulterated.

(2) No person shall manufacture, prepare, store, preserve, package or re-pack any medicine without adhering to Good Manufacturing Practices (GMP) and any other prescribed guidelines or conditions.

(3) No person shall import or distribute any medicine without adhering to Good Distribution Practices (GDP) and any other prescribed guidelines and conditions.

Labelling, &c.,to be in conformity with the prescribed standards.

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

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

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

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

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

(4) No person shall label, package, re-pack, treat, process, sell, distribute, exhibit or advertise any medicine in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding efficacy, quality, composition or safety.

(5) A medicine that is not labeled or packaged in a manner as may be prescribed shall be deemed to be labeled or packaged contrary to subsection (1).

Sale of prescribed medicine is prohibited unless premises and process of manufacture have been approved.

**51.** No person shall sell, exhibit or distribute any medicine as may be prescribed unless the premises in which the medicine was manufactured and the process and conditions of manufacture of that medicine have been approved in the prescribed form and manner as being suitable to ensure that the medicine will be safe for use.

Sale of prescribed medicine prohibited unless the batch from which such medicine is taken approved as reliable.

**52.** No person shall sell, exhibit or distribute any medicine as may be prescribed unless the batch from which that medicine was taken has been approved in the prescribed form and manner as reliable for use.

Sale &c., of prohibited medicine.

**53.** No person shall manufacture, import, store, sell, re-pack, distribute, transport, exhibit or have in his possession any medicine which is prescribed as not safe for use.

Possession of prohibited medicine.

**54.** No person other than the persons as may be permitted by regulations shall obtain or have in his possession any medicine restricted or prohibited by regulations.

Advertising, importation, sale and distribution of medicine as treatment for prescribed diseases prohibited.

**55.** (1) No person shall advertise or promote any medicine without prior written approval of the Authority.

(2) No person shall advertise or promote any medicine to the general public as a treatment, prevention or cure for any of the prescribed diseases, disorders or abnormal physical states.

(3) No person shall, without prior written approval of the Authority, import, sell or distribute any medicine to the general public as a treatment, prevention or cure for any of the prescribed diseases, disorders or abnormal physical states.

Generic name of a medicine to be written in the prescription.

**56.** (1) Every Medical Practitioner, Dentist or Veterinary Surgeon shall write the generic name of the medicine in every prescription issued by him.

(2) Where the Medical Practitioner, Dentist or Veterinary Surgeon so requires, he may in addition to the generic name write a particular brand name of the medicine in the prescription.

(3) A Medical Practitioner, Dentist or Veterinary Surgeon may write only the brand name of a medicine in the prescription where the medicine prescribed is a combined medicine for which the generic name is not available.

(4) Where the brand name of the medicines, which is in the prescription is not available or affordable to the customer, the Pharmacist may dispense any other generic medicine with the consent of the customer.

(5) The Pharmacist shall inform the customer the range of generic medicines with or without brand names available in the Pharmacy and their prices enabling the customer to buy the medicine according to his choice.

(6) A Pharmacist who fails to disclose the generic medicines with or without brand names available in the Pharmacy and their prices to the customer at the time of sale, commits an offence.

Contravention of the provisions of this Part to be an offence.

**57.** Any person who contravenes any of the provisions specified in this Part of this Act commits an offence.

## PART IV

### REGISTRATION AND LICENSING OF MEDICINES

Requirement to register &c., of medicines.

**58.** (1) No person shall manufacture or import any medicine without registering such medicine with the Authority and obtaining a licence from the Authority therefor.

(2) No person shall store, assemble, re-pack, distribute, transport or sell any medicine without obtaining a licence for that purpose from the Authority.

(3) Any person who contravenes any of the provisions specified in subsection (1) or (2) commits an offence.

Application for Registration of a medicine.

**59.** (1) Any person who intends to manufacture or import any medicine shall make an application for the registration of that medicine in the prescribed form to the Authority.

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

(3) (*a*) The Authority shall maintain a register in which every application received for the registration of a medicine shall be recorded.

(*b*) The particulars to be entered in such register shall be as prescribed.

(4) The Authority shall upon receipt of an application submit that application together with the sample of the medicine and all particulars, available -

(*a*) to the MEC, for the evaluation of the application and the medicine considering the need to ensure the availability of efficacious, safe and good quality medicine relevant to the healthcare needs of the public at an affordable price; and

(*b*) to the NMQAL, for testing of the quality of the medicine.

(5) The Authority shall inform the applicant in writing that the application has been received and submitted for evaluation and testing.

(6) The Minister may make regulations -

(*a*) setting out the procedures to be followed, by the MEC and the NMQAL in their respective evaluation and testing processes;

(*b*) specifying –

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

(ii) the manner in which the MEC 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 require the MEC and the NMQAL to finalize the evaluation or testing of a medicine within a specified time period considering the urgency of such medicine for the national health.

(*b*) The MEC and the NMQAL shall within the time limits specified submit their reports to the Authority unless there are compelling reasons for any delay.

Registration of medicines.

**60.** (1) (*a*) The Authority may where necessary, call for clarifications from the MEC, NMQAL or any other expert, with regard to the reports submitted by the MEC and the NMQAL.

(*b*) The Authority may upon taking into consideration the reports submitted by the MEC, NMQAL and all other relevant factors, register such medicine, or refuse the registration, within the stipulated time period.

(2) Where the Authority registers the medicine, such registration shall be informed to the applicant in writing and may inform the public of such registration by order published in the *Gazette.*

Refusal of Registration.

**61.** Where the Authority refuses the registration of the medicine, such refusal shall be communicated to the applicant with reasons therefor within the stipulated time period and shall inform the public of such refusal by order published in the *Gazette*.

Issuing of certificate of registration.

**62.** (1) (*a*) The Authority shall on registration of any medicine, issue a Certificate of Registration to the applicant who shall, hereinafter in this part of this Act, be referred to as "the holder of certificate".

(*b*) The Authority may grant full or provisional registration in respect of the medicine and the conditions for each type of registration shall be prescribed.

(*c*) The period of registration granted shall be decided by the Authority as appropriate.

(2) 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.

(3) Upon obtaining the Certificate of Registration, the holder of certificate shall enter into an agreement with the Authority to inform the Authority of any new developments of the medicine including the changes to indications, side effects, cautions, contra-indications, new recommendations by regulatory bodies in other countries, strictures, cancellations within a stipulated time period upon such facts and information being revealed.

Issuing of licence.

**63.** (1) The Authority may upon issuing the Certificate of Registration, and on the written request by the holder of certificate, issue him a licence to import the medicine and market the medicine in Sri Lanka.

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

Renewal.

**64.** (1) The holder of certificate may make an application to the Authority, for renewal of such registration or the licence six months prior to the date of expiry of such registration or the licence.

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

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

(4) The MEC may, through the Authority, request for samples, documents or any other evidence, which it deems necessary, from the applicant or any other person or institution for the evaluation of the medicine.

(5) The MEC may, where the MEC deems necessary, request the NMQAL to submit an evaluation report on the medicine and the NMQAL shall submit the evaluation report as required by the MEC.

(6) The Authority may upon taking into consideration all relevant factors, renew the registration or the licence for a further period of not less than one year and not exceeding five years.

Cancellation or suspension of registration and licence.

**65.** (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 medicine has been registered;

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

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

(*d*) the medicine has not been imported to Sri Lanka within two years from the date of registration;

(*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 certificate in respect of such medicine.

(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 submit.

(3) Where the holder of certificate fails to submit his comments within the time stipulated therefor or after consideration of any comments submitted, the Authority may suspend or cancel the Certificate of Registration and any related license and inform in writing the 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 or licence of the medicine for which such Certificate relates, shall be deemed to have automatically been cancelled.

CHAPTER IV

## REGULATION AND CONTROL OF ALL ASPECTS PERTAINING TO MEDICAL DEVICES

PART I

MEDICAL DEVICES REGULATORY DIVISION

Medical Devices Regulatory Division.

**66.** (1) The Medical Devices Regulatory Division established under section 30(2) shall hereinafter in this Act be referred to as the MDR Division.

(2) The Authority shall appoint the head of the MDR Division from among persons holding a recognized degree in Medicine, Pharmacology, Pharmacy or any other related discipline.

Functions of the MDR Division.

**67.** (*a*) The principal function of the MDR Division shall be to co-ordinate and assist the Authority to regulate and control all aspects pertaining to medical devices.

(*b*) The other functions of the MDR Division shall be the -

(i) co-ordination of applications submitted for registration of medical devices and renewal of such registration;

(ii) co-ordination of matters pertaining to cancellation or suspension of registration of medical devices;

(iii) co-ordination of matters pertaining to registration of importers and distributers of medical devices;

(iv) co-ordination of the issuance of licences under this section; and

(v) provisions of administrative assistance to the Medical Devices Evaluation Committee appointed under section 68 of this Act.

## PART II

### MEDICAL DEVICES EVALUATION

Medical Devices Evaluation Committee.

**68.** (1) There shall be appointed for the purposes of this Act a Committee which shall be known as the Medical Devices Evaluation Committee (hereinafter referred to as "the MDEC").

(2) (*a*) The principal function of the MDEC shall be to carry out the technical evaluation of the medical devices forwarded for registration and to submit a report in respect thereof to the Authority.

(*b*) The report shall specify the benefits, risks attached to such medical devices, and the efficacy, quality, safety, need and cost of such medical devices with pharmacoeconomic analysis where necessary in keeping with the National Medicines Policy.

Constitution of the MDEC.

**69.** (1) The MDEC shall consist of the following persons who shall be appointed by the Authority-

(*a*) *ex-officio* members-

(i) the head of the MDR Division who shall function as the Chairman of the Committee;

(ii) the Deputy Director General of Laboratory Services of the Ministry;

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

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

(v) the Head of the National Medicines Quality Assurance Laboratory (NMQAL);

(*b*) nominated members-

(i) a Professor or a Senior Lecturer in Pharmacology of any University established under the Universities Act, No. 16 of 1978, nominated by the Deans of Medical Faculties of such Universities;

(ii) a Professor or Senior Lecturer in Pharmacy of any University in Sri Lanka established under the Universities Act, No.16 of 1978, nominated by the Deans of relevant Faculties;

(iii) a Professor or a Senior Lecturer in Biomedical Engineering from any University in Sri Lanka established under the Universities Act, No. 16 of 1978, nominated by the University Grants Commission;

(iv) the Director of the Sri Lanka Standards Institute established under the Sri Lanka Standards Institute Act, No.6 of 1984, or his nominee;

(v) the Director – General of the Sri Lanka Atomic Energy Board and the Director-General of the Sri Lanka Atomic Energy Regulatory Council appointed under the Sri Lanka Atomic Energy Act, No. 40 of 2014, or their nominees;

(vi) a Consultant in Transfusion Medicine, nominated by the Sri Lanka College of Transfusion Physicians;

(vii) a Consultant General Surgeon, nominated by the College of Surgeons of Sri Lanka;

(viii) a Consultant Microbiologist nominated by the Sri Lanka College of Microbiologists;

(ix) a Consultant Biochemist, nominated by the Association of Biochemists;

(x) a Consultant Anesthesiologist, nominated by the Sri Lanka College of Anesthesiologists;

(xi) an Oral Maxillo Facial Surgeon, nominated by the College of Dental Surgeons of Sri Lanka;

(xii) a Consultant Physician nominated by the Ceylon College of Physicians;

(xiii) a Consultant Radiologist nominated by the Sri Lanka College of Radiology; and

(xiv) a Pharmacist in charge of the subject of medical devices in the Authority nominated by the Authority.

(2) The quorum for meetings shall be seven members excluding the members of the Panel of Experts.

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

Panel of Experts.

**70.** (1) The Authority shall appoint a Panel of Experts, comprising of eminent professionals specialized in medical devices.

(2) The Authority may where necessary appoint additional members to the MDEC from the panel of experts, depending on the subject matter dealt with by the MDEC.

(3) The members appointed under subsection (2) shall be present at the meetings for which their presence is required and express their opinion but they shall have no voting rights at such meetings.

Declaration of secrecy.

**71.** Every member of the MDR Division and the MDEC and all officers and employees of the MDR Division and the MDEC shall, before entering upon duties, sign a declaration pledging to observe strict secrecy in respect of all matters connected with the affairs of the MDR division and the

MDEC, which has come to his knowledge in the performance or exercise of his powers and functions under this Act and shall by such declaration pledge himself not to disclose any such matter, except -

(*a*) when required to do so by a court of law; or

(*b*) for the purpose of exercising or performing the powers and functions under this Act or any other written law.

Authority to give general guidelines for the evaluation.

**72.** (1) The Authority shall issue general guidelines to the MDEC for the evaluation of medical devices and other related items, submitted to the MDEC.

(2) (*a*) The general guidelines referred to in subsection (1) shall be based on the Good Manufacturing Practices (GMP) guidelines and other recommendations and guidelines issued or recommended by the Authority.

(*b*) The Authority may revise the general guidelines from time to time in order to maintain parallels with internationally recognized standards and practices.

(3) The MDEC shall take into consideration the efficacy, safety, quality, need and cost of each medical device or related item in the process of evaluation and may consider pharmacoeconomic evaluation where necessary.

(4) The Minister may make regulations -

(*a*) setting out the procedures to be followed, including the specified time limits, for the conduct of respective evaluations;

(*b*) to give effect to the Good Manufacturing Practices (GMP) guidelines and any other applicable guide lines as may be recommended by the Authority;

**73.** The provisions of sections 5, 6, 7, 8, 9, 10, 11, 12 and 13 of this Act shall *mutatis mutandis* apply to and in relation to the Chairman, members and the conducting of the affairs of the MDEC.

Application of certain provisions of this Act in relation to MDEC.

## PART III

### OFFENCES PERTAINING TO THE MEDICAL DEVICES

**74.** (1) The Authority shall list from time to time the medical devices registered under this Act.

Prohibition of importation &c., of medical devices other than the listed.

(2) No person shall import, sell, transport, distribute or advertise any medical device, other than a medical device listed under subsection (1).

**75.** (1) No person shall manufacture, prepare, store, preserve, package or re-pack any medical device without adhering to Good Manufacturing Practices (GMP) and any other prescribed guidelines or conditions.

Regulation of manufacture, importation, sale and distribution of medical devices.

(2) No person shall import or distribute any medical device without adhering to Good Distribution Practices (GDP) and any other prescribed guidelines or conditions.

(3) No person shall sell any medical device without adhering to Good Pharmacy Practices and any other prescribed guideline or condition.

**76.** No person shall manufacture, import, assemble, transport, sell or distribute any medical device that may cause any injury to the health of the user when that medical device is used—

Prohibition of manufacturing, importation, assembling, sale and distribution &c., of medical devices.

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

(*b*) according to the directions on the label accompanying that medical device.

Labeling, packaging and advertising of medical device.

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

Prescribed standards of a medical device to be maintained.

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

Advertising, importation, sale and distribution of medical devices as a treatment for prescribed diseases prohibited.

**79.** (1) No person shall advertise or promote any medical device without prior written approval of the Authority.

(2) No person shall advertise or promote any medical device to the general public as a treatment, prevention or cure for any of the prescribed diseases, disorders or abnormal physical states.

(3) No person shall without prior written approval of the Authority import, sell or distribute any medical device to the general public as a treatment, prevention or cure for any of the prescribed diseases, disorders or abnormal physical states.

Possession of prohibited medical devices.

**80.** No person other than the persons as may be permitted by regulations shall obtain or have in his possession any medical device as may be restricted or prohibited by regulations.

Contravention of the provisions of this Part to be an offence.

**81.** Any person who contravenes any of the provisions specified in this Part of this Act commits an offence.

## PART IV

### Registration and Licensing of Medical Devices

Requirement to register &c., of medical devices.

**82.** (1) No person shall manufacture or import any medical device without registering such medical device with the Authority and obtaining a licence from the Authority therefor.

(2) No person shall store, assemble, re-pack, distribute, transport or sell any medical device without obtaining a licence for that purpose from the Authority.

(3) Any person who contravenes any of the provisions specified in subsection (1) or (2) commits an offence.

Application for Registration of a Medical device.

**83.** (1) Any person who intends to manufacture or import any medical device shall make an application for the registration of that medical device in the prescribed form to the Authority.

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

(3) (*a*) The Authority shall maintain a register in which every application received for the registration and licensing of a medical device shall be recorded.

(*b*) The particulars to be entered in such register shall be as prescribed.

(4) The Authority shall upon receipt of an application submit a copy of that application together with the sample of the medical device and all particulars, available –

(*a*) to the MDEC, for the evaluation of the application and the medical device considering the need to ensure the availability of efficacious, safe and good quality medical device relevant to the healthcare needs of the public at an affordable price; and

(*b*) to the NMQAL, for testing of the quality of the medical device.

(5) The Authority shall inform the applicant in writing of the receipt of the application.

(6) The Minister may make regulations –

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

(*b*) specifying—

(i) the time-limits in conducting such testing or 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 require the MDEC and the NMQAL to finalize the evaluation or testing within a specified time period considering the urgency of the medical device.

(*b*) The MDEC and the NMQAL shall within the time limits specified submit their reports to the Authority unless there are compelling reasons for any delay.

Registration of medical devices.

**84.** (1) (*a*) The Authority may where necessary, call for clarifications from the MDEC, NMQAL or any other expert, with regard to the reports submitted by the MDEC and the NMQAL.

(*b*) The Authority may upon taking into consideration the reports submitted by the MDEC, NMQAL and all other relevant factors register such medical device, or refuse the registration, within the stipulated time period.

(2) Where the Authority registers the medical device, such registration shall be informed to the applicant in writing and may inform the public of such registration by order published in the *Gazette.*

Refusal of Registration.

**85.** Where the Authority refuses the registration of the medical device, such refusal shall be informed to the applicant with reasons therefor within the stipulated time period and shall inform the public of such refusal by Order published in the *Gazette*.

Application of the provisions of sections 62, 63, 64 and 65.

**86.** The provisions of sections 62, 63, 64 and 65 of this Act shall *mutatis mutandis* apply to and in relation to—

(*a*) the issuing of certificate of registration;

(*b*) issuing of licence;

(*c*) renewal of registration or licence;

(*d*) cancellation or suspension of registration or licence,

under this part of this Act.

## CHAPTER V

## REGULATION AND CONTROL OF ALL ASPECTS PERTAINING TO BORDERLINE PRODUCTS

### PART I

### BORDERLINE PRODUCTS REGULATORY DIVISION

Borderline Products Regulatory Division.

**87.** (1) The Borderline Products Regulatory Division established under section 30(2) shall hereinafter in this Act be referred to as the BPR Division.

(2) The Authority shall appoint the head of the BPR division from among persons holding a recognized degree in Medicine, Pharmacology, Pharmacy or any other related discipline.

Functions of the BPR Division.

**88.** (*a*) The principal function of the BPR division shall be to co-ordinate and assist the Authority to regulate and control all aspects pertaining to borderline products.

(*b*) The other functions of the BPR division shall be the—

(i) co-ordination of applications submitted for registration of borderline products and renewal of such registration;

(ii) co-ordination of matters pertaining to cancellation or suspension of registration of borderline products;

(iii) co-ordination of matters pertaining to registration of importers and distributers of borderline products;

(iv) co-ordination of the issuance of licences under this section;

(v) provisions of administrative assistance to the Borderline Products Evaluation Committee appointed under section 89 of this Act.

## PART II

### BORDERLINE PRODUCTS EVALUATION

Borderline Products Evaluation Committee.

**89.** (1) There shall be appointed for the purposes of this Act a Committee which shall be known as the Borderline Products Evaluation Committee (hereinafter referred to as "the BPEC").

(2) (*a*) The principal function of the BPEC shall be to carry out the technical evaluation of the borderline products forwarded for registration and submit a report in respect thereof to the Authority.

(*b*) The report shall specify the benefits, risks attached to such borderline products, and the efficacy, quality, safety, need and cost of such borderline products with pharmacoeconomic analysis where necessary in keeping with the National Medicines Policy.

Constitution of the BPEC.

**90.** (1) The BPEC shall consist of the following persons who shall be appointed by the Authority—

(*a*) ex-officio members—

(i) the head of the BPR Division who shall function as the Chairman of the Committee;

(ii) the head of the National Medicines Quality Assurance Laboratory (NMQAL);

(iii) the Government Analyst or his nominee;

(*b*) nominated members-

(i) a Professor or a Senior Lecturer in Pharmacology of any University established under the Universities Act, No. 16 of 1978, nominated by the Deans of Medical Faculties;

(ii) a Professor or a Senior Lecturer in Pharmacy of any University in Sri Lanka established under the Universities Act, No.16 of 1978, nominated by the Deans of relevant Faculties of such Universities;

(iii) a Pharmacist of the Authority;

(iv) a Nutritionist from the Ministry of Health to be nominated by the Director General of Health Services;

(v) the Director of the Sri Lanka Standards Institute established under the Sri Lanka Standards Institute Act, No. 6 of 1984 or his nominee;

(vi) the Director of the Industrial Technology Institute or his nominee;

(vii) a representative from the Consumer Affairs Authority established under the Consumer Affairs Authority Act, No. 9 of 2003 nominated by the Chairman; and

(viii) a representative of Ayurveda Department nominated by the Commissioner of Ayurveda.

(2) The quorum for meetings shall be five members excluding the members of the Panel of Experts.

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

Panel of Experts.

**91.** (1) The Authority shall appoint a Panel of Experts, comprising of eminent professionals specialized in borderline products.

(2) The Authority may where necessary appoint additional members to the BPEC from the panel of experts, depending on the subject matter dealt with by the BPEC.

(3) The members appointed under subsection (2) shall be present at the meetings for which their presence is required and express their opinion but they shall have no voting rights at such meetings.

Declaration of secrecy.

**92.** Every member of the BPR division and the BPEC and all officers and employees of the BPR division and the BPEC shall, before entering upon duties, sign a declaration pledging to observe strict secrecy in respect of all matters connected with the affairs of the BPR division and the BPEC, which has come to his knowledge in the performance or exercise of his powers and functions under this Act and shall by such declaration pledge himself not to disclose any such matter, except—

(*a*) when required to do so by a court of law; or

(*b*) for the purpose of exercising or performing the powers and functions under this Act or any other written law.

Authority to give general guidelines for the evaluation.

**93.** (1) The Authority shall issue general guidelines to the BPEC for the evaluation of borderline products and other related items, submitted to the BPEC.

(2) (*a*) The general guidelines referred to in subsection (1), shall be based on the Good Manufacturing Practices (GMP) guidelines and other recommendations issued by the World Health Organization and other regulatory bodies recognized by the Authority.

(*b*) The Authority may revise the general guidelines from time to time in order to maintain parallels with internationally recognized standards and practices.

(3) The BPEC shall take into consideration the efficacy, safety, quality, need and cost of each borderline product, in the process of evaluation.

(4) The Minister may make regulations—

(*a*) setting out the procedures to be followed, including the specified time limits for the conduct of respective evaluations;

(*b*) to give effect to the Good Manufacturing Practices (GMP) guidelines and any other applicable guide lines as may be recommended by the Authority.

Application of certain provisions of this Act in relation to BPEC.

**94.** The provisions of sections 5, 6, 7, 8, 9, 10, 11, 12 and 13 of this Act shall *mutatis mutandis* apply to and in relation to the Chairman, members and the conducting of the affairs of the BPEC.

## PART III

### OFFENCES PERTAINING TO BORDERLINE PRODUCTS

Prohibition of importation &c., of borderline products other than listed.

**95.** (1) The Authority shall list from time to time the borderline products registered under this Act.

(2) No person shall import, sell, transport, distribute or advertise any borderline product, other than a borderline product listed under subsection (1).

Regulation of manufacture, importation, sale and distribution of borderline products.

**96.** (1) No person shall import, distribute, re-pack or sell any borderline product which—

(*a*) is not manufactured, prepared, preserved, packaged or stored under good manufacturing practices and good storage practices;

(*b*) consists in whole or in part of any contaminant material, foreign body 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 borderline product is used—

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

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

(2) No person shall label, package, treat, process, transport, distribute, sell, exhibit or advertise any borderline product in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its efficacy, safety, quality or composition.

(3) No person shall manufacture any borderline product unless Good Manufacturing Practices (GMP) and Good Storage Practices (GSP) are complied with.

Where standard is prescribed for borderline products.

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

Advertising, importation, sale and distribution of borderline products for prescribed diseases prohibited.

**98.** (1) No person shall advertise or promote or distribute any borderline product without prior written approval of the Authority.

(2) No person shall advertise or promote any borderline product to the public as a treatment, prevention or cure for any of the prescribed diseases, disorders or abnormal physical states.

(3) No person shall without prior written approval of the Authority import, sell or distribute any borderline product to the general public as a treatment, prevention or cure for any of the prescribed diseases, disorder or abnormal physical states.

Possession of prohibited borderline product.

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

Contravention of the provisions of this Part to be an offence.

**100.** Any person who contravenes any of the provisions specified in this Part of this Act commits an offence.

## PART IV

### Registration and Licensing of Borderline Products

Requirement to register &c., of borderline products.

**101.** (1) No person shall manufacture or import any borderline product without registering such borderline product with the Authority and obtaining a licence from the Authority therefor.

(2) No person shall store, assemble, re-pack, distribute, transport or sell any borderline product without obtaining a licence for that purpose from the Authority.

(3) Any person who contravenes any provision specified in subsection (1) or (2) of this section commits an offence.

Application for Registration of a borderline product.

**102.** (1) Any person who wishes to import, sell, manufacture, prepare or distribute any borderline product shall make an application for the registration of that borderline product in the prescribed form to the Authority.

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

(3) (*a*) The Authority shall maintain a register in which every application received for the registration and licensing of a borderline product shall be recorded.

(*b*) The particulars to be entered in such register shall be as prescribed.

(4) The Authority shall upon receipt of an application submit the application together with the sample of the borderline products and all particulars, available -

(*a*) to the BPEC, for the evaluation of the application and the borderline products considering the need to ensure the availability of efficacious, safe and good quality borderline products relevant to the healthcare needs of the public at an affordable price; and

(*b*) to the NMQAL or where necessary any other laboratory for testing of the quality of the borderline product.

(5) The Authority shall inform the applicant in writing of the receipt of the application.

(6) The Minister may make regulations -

(*a*) setting out the procedures to be followed, by the BPEC and the NMQAL in their respective evaluation and testing processes;

(*b*) specifying –

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

(ii) the manner in which the BPEC 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 require the BPEC and the NMQAL to finalize the testing or evaluation within a specified time period considering the urgency of the borderline product for the national health.

(*b*) The BPEC and the NMQAL shall within the time limits specified submit their reports to the Authority unless there are compelling reasons for any delay.

Registration of borderline products.

**103.** (1) (*a*) The Authority may where necessary, call for clarifications from the BPEC, NMQAL or any other expert, with regard to the reports submitted by the BPEC and the NMQAL.

(*b*) The Authority may upon taking into consideration the reports submitted by the BPEC, NMQAL and all other relevant factors register such borderline product or refuse the registration, within the stipulated time period.

(2) Where the Authority registers the borderline product, such registration shall be informed to the applicant in writing and may inform the public of such registration by Order published in the *Gazette*.

Refusal of Registration.

**104.** Where the Authority refuses the registration of the borderline product, such refusal shall be informed to the applicant with reasons therefor within the stipulated time period and shall inform the public of such refusal by Order published in the *Gazette*.

Application of the provisions of sections 62, 63, 64 and 65.

**105.** The provisions of sections 62, 63, 64 and 65 of this Act shall *mutatis mutandis* apply to and in relation to the —

(i) issuing of certificate of registration;

(ii) issuing of licence;

(iii) renewal of registration and licence; and

(iv) cancellation or suspension of registration or licence,

under this part of this Act.

CHAPTER VI

## COLLECTIVE PROVISIONS PERTAINING TO MEDICINES, MEDICAL DEVICES AND BORDERLINE PRODUCTS

PART I

COMMON PROVISIONS

Prohibition of dishonest dealings.

**106.** (1) No person shall store, re-pack, assemble, transport, distribute or sell any illegal, counterfeit or smuggled, medicine, medical device or borderline product.

(2) (*a*) No person shall import, distribute, re-pack, display or sell any medicine, medical device or borderline product after the expiry date of such medicine, medical device or borderline product.

(*b*) No person shall store any medicine, medical device or borderline product after the expiry date of such medicine, medical device or borderline product except under conditions stipulated by the Authority.

(3) No person shall without lawful authority import, store, assemble, transport, distribute, re-pack, display or sell any medicine, medical device or borderline product containing the State logo or any other mark indicating that such products are a State property.

Authority to decide residual shelf-life of medicines &c.

**107.** (1) The Authority shall, decide the residual shelf-life of every medicine, medical device or borderline product imported into Sri Lanka at the port of entry.

(2) It shall be the responsibility of the importer to ensure quality, safety and efficacy of every medicine, medical device or borderline product imported by him.

Ban or withdrawal &c.,from, use of medicine &c.

**108.** (1) The Authority shall, where the Authority finds that any medicine, medical device or borderline product does not meet the required standard or that the medicine, medical device or the borderline product as manufactured would cause serious health problems to the person using, issue an order requiring the importer, manufacturer, trader or distributor of that medicine, medical device or borderline product 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 medicine, medical device or borderline product.

(2) The Authority shall cause notice of the ban or withdrawal from use of medicine, medical device or borderline product in terms of this section, to be published in a daily newspaper in Sinhala, Tamil and English 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 million rupees or to an imprisonment of either description for a period not exceeding three years or to both such fine and imprisonment.

Emergency and other special circumstances.

**109.** (1) The Authority may grant permission in special circumstances such as to save a life, 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 medicine, medical device or borderline product in specified quantities.

(2) Such permission may be granted:—

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

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

(3) The importer shall be responsible for the accountability and management of the medicine, medical device or borderline product imported under this section.

(4) The importer shall submit routine reports in the prescribed manner to the Authority, on the medicine, medical device or borderline product imported under this section.

Sale or distribution of samples of medicine &c., to be prohibited.

**110.** (1) (*a*) No person shall distribute any medicine, medical device or borderline product marked as Physician's sample to the general public.

(*b*) The provisions of paragraph (*a*) shall not apply to the distribution of any medicine, medical device or borderline product marked as physician, sample by a Medical Practitioner, Dentist or Veterinary Surgeon to a patient of such Medical Practitioner, Dentist or Veterinary Surgeon.

(2) (*a*) No person shall transport, exhibit or store any medicine, medical device or borderline product marked as a Physician's sample.

(*b*) The provisions of paragraph (*a*) shall not apply to any representative of a company duly authorized by the Authority.

(3) No person shall sell any medicine, medical device or borderline product marked as a physician's sample.

Permission to import and to accept as a donation of any medicine &c.

**111.** (1) Subject to the provisions of subsection (3) no person shall import or accept as a donation any medicine, medical device or borderline product for free distribution or to promote within Sri Lanka, without the approval of the authority.

(2) The provisions of subsection (1) shall apply to the importation or receiving of medicine, medical device or borderline product as a donation during an emergency or disaster situation.

(3) Minister may, prescribe the guidelines, for accepting donations of medicines, medical devices or borderline products at any disaster or emergency situation, taking into consideration the guidelines of the World Health Organization issued in relation to accepting or receiving medicines, medical devices or borderline products during similar situations.

Importation &c., of medicines &c., for personal use.

**112.** (1) The provisions of sections 58, 82 and 101 shall not apply to any patient who needs for his personal medication a medicine, medical device or borderline product which is not registered and licensed under this Act.

(2) Such person may import the required quantity of such medicine, medical device or borderline product on a prescription issued by the medical practitioner treating him, with the prior approval of the Authority.

(3) It shall be an offence to sell any medicine, medical device or borderline product manufactured or imported under this section.

Licensing of premises for manufacturing &c., of medicine &c.

**113.** (1) No person shall manufacture, prepare, store or sell any medicine, medical device or borderline product in any premises unless such premises has been licensed in that regard by the Authority.

(2) (*a*) No person shall store or sell any medicine, medical device or borderline product, in any premises unless such premises has been licensed by the Authority.

(*b*) The provisions of paragraph (*a*) shall not apply to—

(i) any patient who keeps any medicine, medical device or borderline product registered under this Act, for his personal use;

(ii) any medicine, medical device or borderline product prescribed by regulations as safe for general use.

(3) The Authority shall maintain a register of registered manufacturers and importers and the criteria for registering shall be as prescribed.

Conditions &c., pertaining to licence.

**114.** (1) Every licence granted under this Act shall—

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

(*b*) be subject to such conditions as may be prescribed;

(*c*) unless cancelled earlier, be in force for such period as may be specified in such licence.

(2) A licence granted under this Act may be suspended or revoked by the Authority in case of non-compliance with the prescribed conditions.

(3) An applicant may at any time withdraw an application for a licence by notifying the Authority in writing, without prejudice to his right to re-apply for a licence.

## PART II

## Regulation of Manufacturing of Medicines, Medical Devices and Borderline Products

Establishment of the Manufacturing Regulatory Division.

**115.** (1) The Authority shall establish for the purpose of this Act a Division to be known as Manufacturing Regulatory Division.

(2) The Authority shall appoint the head of that Division from among persons holding a recognized degree in Pharmacology, Pharmacy or any other related subject.

Functions of the Manufacturing Regulatory Division.

**116.** (1) The principal function of the Manufacturing Regulatory Division shall be the regulation of manufacturing of medicines, medical devices and borderline products in Sri Lanka.

(2) The other functions of the Manufacturing Regulatory Division shall be to—

(*a*) formulate schemes to provide all necessary assistance including technical knowhow to the prospective manufacturers;

(*b*) provide necessary assistance to the manufacturers to market their products locally;

(*c*) provide necessary assistance to manufacturers to export their products;

(*d*) advise the Authority to restrict the importation of certain products where locally manufactured products are sufficiently available in Sri Lanka.

(3) For the purpose of this section "product" means a medicine, medical device or borderline product.

Regulations.

**117.** Minister may make regulations to give effect to all or any of the provisions of this Part of this Act.

## PART III

## Pricing of Medicines, Medical Devices and Borderline Products

Pricing of medicines &c.

**118.** (1) (*a*) The Authority shall appoint a Committee to be known as the Pricing Committee.

(*b*) The composition, powers and functions of the Pricing Committee shall be as prescribed.

(2) (*a*) The Authority shall in consultation with the Pricing Committee, determine the introductory price of medicines, medical devices and borderline products at the time of registration, based on the criteria as may be prescribed.

(*b*) For the purpose of paragraph (*a*), the Authority shall consider the prevailing market prices of similar products within the same therapeutic class, International Reference Prices and other factors as may be prescribed.

(3) For the purpose of determining the prices of New Chemical Entities, the Authority shall consider the prices in the region, the benefit of the new product and the cost effectiveness.

(4) The Minister shall in consultation with the Pricing Committee, the Consumer Affairs Authority and all stakeholders and taking into consideration all other relevant factors including the provisions of the Consumer Affairs Authority Act, No. 9 of 2003, prescribe a pricing mechanism for medicines, medical devices and borderline products.

## CHAPTER VII

## MISCELLANEOUS

### PART I

### REGULATION OF PHARMACIES

Every person to carry on a Pharmacy to obtain a licence.

**119.** (1) No person shall carry on a Pharmacy without obtaining a licence from the Authority.

(2) Any person who intends to carry on a Pharmacy shall make an application for that purpose in the prescribed form to the Authority.

(3) The application shall contain all such information and be forwarded with all such documents as may be set out in such form and be accompanied by the prescribed fee.

(4) The Authority may on receipt of an application refer the application to the Pharmacies Regulatory Division for their observations which shall be submitted within a specified time period.

(5) The Authority may upon consideration of all records and information pertaining to the application,

(*a*) grant the applicant the licence; or

(*b*) refuse the application and inform the reason for such refusal to the applicant in writing forthwith.

(6) The holder of a licence shall before the commencement of the business of a Pharmacy shall register the premises where the Pharmacy is to be carried on.

(7) The Minister shall by regulations prescribe the terms and conditions of a licence and the conditions to be satisfied to register a Pharmacy.

(8) For the purpose of this part of this Act, "holder of licence" means the person granted a licence to carry on a Pharmacy under this section.

Requirement to comply with Good Pharmacy Practices.

**120.** (1) Every person who carries on a Pharmacy shall comply with Good Pharmacy Practices and other guidelines and conditions prescribed by the Authority.

(2) The holder of licence shall employ at least one Pharmacist in the pharmacy to be responsible for all operations of the Pharmacy relating to medicines, medical devices or borderline products.

(3) The dispensing of medicines, medical devices or borderline products shall be carried out by the Pharmacist or a registered apprentice Pharmacist under the direct supervision of the Pharmacist.

(4) The Pharmacist shall before the sale of every medicine, medical device or borderline product, inform the buyer the cost of such medicines, medical device or borderline products.

(5) The Pharmacist shall when dispensing the medicine, medical device or borderline product provide the customer with a description of such medicine, medical device or borderline product, in the language requested for by such customer.

Regulations.

**121.** Minister may make regulations to give effect to all or any of the provisions of this Part of this Act.

## PART II

### APPEALS

Appeals.

**122.** (1) (*a*) Any person aggrieved by any decision of the Authority made under this Act may appeal in writing to the Authority to reconsider such decision within one month of the receipt of such decision.

(*b*) The Authority shall as soon as practicable inform its decision on such appeal to the appellant.

(2) Where the appellant is dissatisfied with the decision of the Authority, the appellant may appeal against such decision to the Appeals Committee appointed under section 123.

The Appeals Committee.

**123.** (1) The Minister shall appoint an Appeals Committee to hear and determine appeals made in terms of this Act.

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

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

(*b*) the Secretary of Health; and

(*c*) a member appointed from among retired Medical Consultants 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, after studying the appeal, call for further information regarding the medicine, medical device or borderline product in question from the appellant and respective Divisions established under this Act and may call for expert opinion on such medicine, medical device or borderline product.

(6) The Appeals Committee shall on consideration of all relevant factors inform its decision to the Authority.

(7) Upon receiving the decision of the Appeals Committee, the Authority shall inform the appellant the decision of the Appeals Committee forthwith and act in accordance with the decision of the Appeals Committee.

(8) The members of the Appeal Committee may be paid such remuneration out of the Fund of the Authority with the concurrence of the Minister assigned of the subject of Finance.

## PART III

### POWERS AND FUNCTIONS OF THE AUTHORIZED OFFICERS

Authorized Officers.

**124.** (1) The Minister may appoint any Provincial Director of Health Services, any Regional Director of Health Services, any Medical Officer of Health, any Divisional Pharmacist, any Food and Drugs Inspector, Drugs Inspector or any Pharmacist attached to the Authority to be an "Authorized Officer" for the purposes of this Act.

(2) Every Authorized Officer shall exercise the powers of a peace 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.

Powers of Authorized Officers.

**125.** (1) An Authorized Officer, for the performance of his duties and the exercise of his powers under the Act may-

(*a*) enter at any reasonable hour to any place where he believes any article is manufactured, prepared, packaged, re-packed, preserved, sold or stored and examine any such article and take samples thereof, and examine anything that he believes is used for the manufacture, preparation, packaging, preservation 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 vehicle in which he believes that any article is being conveyed, search that vehicle and examine such article and take samples of the said article;

(*d*) examine any book, document or other records including electronic data found 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 regulation 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 regulation 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 functioning under the Ministry of Health or the Provincial Health Services.

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

Procedure in respect of articles and vehicles seized.

**126.** (1) Upon the receipt of any information under section 125 (9) where the Authority is 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 the 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 the 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.

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

**127.** (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 on his own motion and shall, at the request of any party to the prosecution, forward for analysis or examination such part of the sample produced in court under subsection (1), to the Approved Analyst.

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

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

Copy or extract of document taken by an Authorized Officer.

**128.** A copy made or extract taken from any book, document or record by an Authorized Officer under section 125(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.

Analysis.

**129.** (1) An Authorized Officer shall submit any article seized by him or any portion thereof or any sample taken by him to the Authority and, unless destroyed under section 126 (1), to the Approved Analyst for analysis or examination, as decided by the Authority.

(2) Where the Approved Analyst has made an analysis or examination of the article 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 part of this Act-

"Approved Analyst" includes an Additional Approved Analyst; and

"article" means medicine, medical device or borderline product.

## PART IV

### General Offences

General offences.

**130.** Every person who—

(*a*) being a person acting under the authority of this Act, discloses any information obtained by him in or in connection with the exercise of his powers or the discharging of his functions under this Act, to any person for any purpose other than a purpose for which he is authorized to disclose such information;

(*b*) obstructs, without any justifiable or lawful basis, any person acting in the exercise of his powers under this Act or any regulation made thereunder;

(*c*) being a person acting under the authority of this Act, behaves or conducts himself in a vexatious or

provocative manner, while exercising or discharging any power or function under this Act; or

(*d*) fails to furnish any return or information in compliance with any requirement imposed on him under this Act or knowingly makes any false statement in any return or information furnished by him,

shall be guilty of an offence under this Act.

Punishment for the contravention of the provisions of this Act.

**131.** (1) Every person who contravenes any of the provisions of this Act or any regulation made thereunder shall be guilty of an offence and shall on conviction be liable—

(*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 that a medicine, medical device or borderline product to be state property, 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 carrying on a Pharmacy 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*) to publish an apology in addition to the punishment mentioned in paragraphs (*a*), (*b*), (*c*) and (*d*) to the general public in one Sinhala, Tamil and English newspaper each, circulating in Sri Lanka substantially in the size of 10"x 10" in front page to the effect that he shall not repeat the offence.

(2) Where a person convicted of an offence under this Act or any regulation 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 medicine, medical device or borderline product under this Act or any other law and inform the relevant licensing Authority accordingly.

(3) Where a person is 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 medicine, medical device or borderline product which is marked state logo or any other marking indicating that such medicine, medical device or borderline product is 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.

(4) 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.

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

**132.** Every person who commits an offence under this Act or any regulation 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.

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

**133.** (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.

Defence.

**134.** (1) In a prosecution for the offence of sale of any medicine, medical device or borderline product contrary to the provisions of this Act or any regulation made thereunder, subject to subsection (2) it shall be a defence for the accused—

(*a*) that he purchased the medicine, medical device or borderline product 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 medicine, medical device or borderline product would be in contravention of the Act or any regulation 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 he purchased the medicine, medical device or borderline product and the date of purchase.

Presumptions.

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

(*a*) any medicine, medical device or borderline product 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; and

(*b*) any substance capable of being used in the composition or preparation of any medicine, medical device or borderline product which is found in the premises and used in a preparation shall be presumed until the contrary is proved, to be intended for use in the composition or preparation of that medicine, medical device or borderline product.

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

(*a*) that such medicine 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 medicine was adulterated by the addition of that other substance.

(3) Where a package containing any medicine, medical device or borderline product 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 medicine, medical device or borderline product was manufactured or packaged, as the case may be, by the person whose name or address appears on the package.

Offence committed by body of persons.

**136.** Where an offence under this Act or any regulation made thereunder is 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 V

## GENERAL

Approved Analyst.

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

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

(3) Notwithstanding the provisions of subsections (1) and (2), the Minister may approve any other laboratory or institution recommended by the Authority to be an Additional Approved Analyst and notification of the approval shall be published in the *Gazette*.

(4) No person, laboratory or institution shall be approved as an Additional Approved Analyst-

(*a*) if that person, the laboratory or institution does not possess the prescribed qualifications or facilities as the case may be; or

(*b*) if that person is engaged directly or indirectly in any trade or business connected with the manufacture, importation, sale or distribution of medicine, medical device or borderline product.

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

**138.** (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, 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 produced a copy of the report or the certificate and reasonable notice of his intention to produce it.

Priority for trial and appeal under this Act.

**139.** Every Court shall give priority to the trial 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.

Application of other written laws.

**140.** (1) The provisions of this Act and any regulation made thereunder relating to medicine 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 regulation made thereunder relating to the importation of any medicine, medical device or borderline product.

(3) For the purposes of the application of the Customs Ordinance to any medicine, medical device or borderline product the importation of which is prohibited under this Act, medicine, medical device or borderline product shall be deemed to be goods the importation of which is prohibited under that Ordinance.

## PART VI

### RULES AND REGULATIONS

Rules.

**141.** (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.

Regulations.

**142**. (1) The Minister may make regulations in respect of any matter required by this Act to be prescribed or in respect of which regulations are authorized by this Act to be made.

(2) In particular and 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 medicine, medical device or borderline product or class of medicine, medical device or borderline product is adulterated if any prescribed substance or class of substance is present or has been added to or extracted from or omitted in, that medicine, medical device or borderline product;

(*b*) declaring that any medicine, medical device or borderline product is safe for general use or not safe for general use;

(*c*) pricing of medicines, medical devices and borderline products;

(*d*) the labeling and packaging and the offering, exposing and advertising for sale of medicine, medical device or borderline product;

(*e*) prescribing the size, dimensions, fill and other specifications of packages of, medicine, medical device or borderline product;

(*f*) the use of any substance as an ingredient in medicine, medical device or borderline product to prevent the user or purchaser from being deceived or misled as to its quality, character, value, composition or to prevent injury to the health of the user or purchaser;

(*g*) the standards of composition, strength, potency, purity, quality or other property of medicine, medical device or borderline product;

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

(*i*) (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;

(*j*) requiring persons who manufacture or sell any medicine, medical device or borderline product to furnish information and maintain books and records;

(*k*) the registration and regulation of Pharmacies and drug stores;

(*l*) the terms and conditions for storage and transport of medicine, medical device, borderline product or investigational medicinal product;

(*m*) the disposal of medicine, medical device, borderline product or investigational medicinal product;

(*n*) the specification of recalling procedure of medicines, medical devices and borderline products and composition of committees;

(*o*) the conditions relating to importers and market authorization holders;

(*p*) the procedure for parallel imports and licensing for non-commercial use by the Government;

(*q*) Forms to be used for the registration, renewal and licensing under this Act and the regulations made thereunder;

(*r*) prohibition and restrictions relating to the sale and transport for sale of any adulterated medicine or borderline product;

(*s*) prescribing the medicines, medical devices or borderline products prohibited under the Act;

(*t*) the distribution and the conditions of distribution of sample of any medicine, medical device, borderline product or investigational medicinal product;

(*u*) the mode and manner in which any medicine, medical device or borderline product shall be registered, the terms and conditions applicable to such registration and licensing, the fees to be levied for such registration or licensing;

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

(*w*) the standards of shelf-life for manufacture of medicines, medical devices or borderline products;

(*x*) procedure to be followed by the MEC, MDEC and BPEC in the conduct of its functions and the transaction of its business;

(*y*) the procedure of inquiries;

(*z*) the procedure to be followed by MEC, MDEC and BPEC for the respective evaluations and matters which should be included in reports;

(*aa*) the review and revision of all guidelines formulated under this Act;

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

(*cc*) evaluation of advertisements and other promotional material of manufacturers, importers, distributors and retailers of medicines, medical devices and borderline products;

(*dd*) regulation of promotional activities pertaining to medicines, medical devices, borderline products and investigational medicinal products;

(*ee*) any other matters as may be necessary for the purposes of achieving the objects and discharging the functions of the Authority.

(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 later date as may be specified in such regulation.

(4) Every regulation made by the Minster, 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*.

Institution of proceedings.

**143.** (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 analysed, after the expiration of a period of one month from the date of the receipt of Analyst's report on such sample.

(2) No civil or criminal proceedings shall be instituted against person for any act which in good faith is done or purported to be done by him under this Act or any regulation make thereunder.

## PART VII

### Repeals and Transitional Provisions

Repeal of Act, No. 27 of 1980.

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

Transitional provisions.

**145.** Notwithstanding the repeal of Cosmetics, Devices and Drugs Act, No. 27 of 1980 (hereinafter referred to as "the repealed Act"), -

(*a*) all contracts and agreements entered into under the repealed Act and subsisting on the day immediately preceding the appointed date shall, with effect from the appointed date, be contracts and agreements entered into under this Act with or on behalf of the Authority and may be enforced accordingly;

(*b*) 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 shall with effect from the appointed date be deemed to have been instituted by or against the Authority and may be continued accordingly;

(*c*) 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 preceding the appointed date shall with effect from the appointed date be deemed to have been made in favor of or against the Authority, and may be enforced accordingly;

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

(*e*) 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 with effect from the appointed date be deemed to be a licence or registration granted by the Authority under the provisions of this Act;

(*f*) every application for a licence or registration of a medicine, medical device or borderline product made to the Cosmetics, Devices and Drugs Authority under the provisions of the repealed Act shall with effect from the appointed date be deemed to be an application made to the Authority established under this Act and shall be dealt with accordingly;

(*g*) 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, be vested with the Authority;

(*h*) all sums 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 under section 18 of this Act;

(*i*) 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 from the appointed date, to be declarations, notifications, licences and orders made or issued under the provisions of this Act and shall be construed accordingly;

(*j*) every reference to the Cosmetics, Devices and Drugs Authority in any written law, notice, notification, instrument, contract, communication or other

document shall with effect from the appointed date be read and construed as a reference to the Authority established under this Act; and

(*k*) every reference to the National Druge Quality Assurance Laboratory of the Cosmetics, Devices Drugs Authority in any written law, notice, notification, contract, communication or other document shall with effect from the appointed date be read and construed as a reference to the NMQAL of the Authority established under this Act.

## PART VIII

### INTERPRETATION

Interpretation.

**146.** In this Act, unless the context otherwise requires:—

"adulterated" means the addition of any substance to or subtraction of any constituent from a medicine, medical device or borderline product 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 medicine medical device or borderline product;

"article" means —

(*a*) any medicine, medical device or borderline product;

(*b*) anything used or capable of being used for the manufacture, preparation, preservation, packaging or storing of any medicine, medical device or borderline product ; and

(*c*) any labeling or advertising material;

"bioequivalence" means two pharmaceutically equivalent or pharmaceutical alternative products having their bio availabilities after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, will be essentially the same. This is considered demonstrated if the 90% confidence intervals (90% CI) of the ratios for $AUC_{0-t}$ and $C_{max}$ between the two preparations lie in the range 80.00 – 125.00%;

"biowaiver" means a regulatory approval process when the application (dossier) is approved on the basis of evidence of equivalence other than an in vivo bioequivalence test. For solid oral dosage forms, the evidence of equivalence is determined on the basis of an in vitro dissolution profile comparison between the multisource and the comparator product;

"borderline products" means the products having combined characteristics of medicines and foods, medicines and medical devices or medicines and cosmetics and in deciding whether a product is a borderline product the following shall be taken into consideration:-

(*a*) the intended use of the product (or its primary function) and its mode of action;

(*b*) the therapeutic claims that the manufacturer makes about the product (claims to treat or prevent disease or to interfere with the normal operation of a physiological function of the human body);

(*c*) the pharmacological active substance(*s*), if any, used in the product;

(*d*) the concentration of the active substances;

(*e*) the level of efficacy of the active substance of the product; and

(*f*) the ingredients used and the concentrations at which they are used;

"Cosmetics" means any substance or mixture of substances manufactured, sold or represented for use in cleaning, improving or altering the complexion, skin, hair or teeth and includes deodorants, perfumes and cosmeceuticals;

"Cosmetics, Devices and Drugs Authority" means Cosmetics, Devices and Drugs Authority established under the Cosmetics, Devices and Drugs Act, No. 27 of 1980;

"counterfeit medical device" means a device which is labeled or packaged fraudulently with regard to identification;

"counterfeit medicine" means a medicine 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 (Chapter 105);

"Drug Inspector" mean any person with prescribed qualifications appointed as a drug inspector by the Authority;

"exhibit" refers to a public display of medicines, medical devices or borderline products at a conference, exhibition or trade fair;

"Generic medicine" means a medicine that-

(*a*) has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the registered medicine;

(*b*) has the same pharmaceutical form;

(*c*) is bioequivalent; and

(*d*) has the same safety and efficacy properties;

"Good Distribution Practice" means good distribution practice guidelines issued by the Authority;

"Good Manufacturing Practice Guidelines" means good manufacturing guidelines issued by World Health Organization;

"Good Pharmacy Practice" means good Pharmacy practice guidelines issued by the Authority;

"Good Storage Practice" means good storage practice guidelines issued by the Authority;

"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 medicine, medical device or borderline product with dirt or filth or render same injurious to health;

"investigational medicinal product" means a product which is under investigation by a clinical trial or equivalent studies which may include a medicine, medical device or a borderline product;

"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 medicine, medical device or borderline product;

"labeling" includes the label and any written printed or graphic matter relating to and accompanying the medicine, medical device or borderline product;

"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 device" means any instrument, apparatus, appliance, software, material or any other article, whether used single or in combination, including the software necessary for its proper application intended by the manufacturer used in or on human beings for the purpose of:-

(*a*) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(*b*) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

(*c*) investigation, replacement or modification of the anatomy or of a physiological process;

(*d*) control of conception,

and which does not achieve its intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its function by such means;

a medical device does not include an Ayurveda device or a Homeopathy device;

"medical practitioner" means a person registered as a medical practitioner under section 29 or section 41 of the Medical Ordinance (Chapter 105);

"medicine" means—

(*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 states or the symptoms thereof in man or animal; and

(ii) restoring, correcting or modifying functions of organs in man or animal;

(*b*) a medicine or combination of medicine ready for use and placed on the market under a special name or in a characteristic form, both patent and non-proprietary preparations;

(*c*) a product made out of medicinal herbal extract;

(*d*) nutraceutical with therapeutic claims; and

(*e*) vaccines and sera,

but does not include an Ayurvedic medicine or Homoeopathic medicine;

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

"need" refers to circumstances in which a product is necessary because it is essential or very important rather than just desirable;

"nutraceutical" 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 medicine, medical device or borderline product is wholly or partly contained, placed or packed;

"person" includes a company;

"Pharmacist" means a Pharmacist registered under the Medical Ordinance (Chapter105);

"prescribed" means prescribed by rules or regulations made under this Act;

"prescription" means an authorization in writing to a Pharmacist from a person authorized by law to prescribe medicines or medical devices to dispense a specified medicine or medical device for use by a designated individual or for animal use;

"prohibited medicine, medical device or borderline product" 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 by way of exchange and whether by wholesale or retail and the term "sale" shall be construed accordingly;

"smuggled medicine, medical device or borderline product" means a medicine, medical device or borderline product imported or brought in to the country in contravention of the provisions of this Act and without obtaining an import license from the Authority; and

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

In case of an inconsistency the Sinhala text shall prevail.

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

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