

PARLIAMENT OF THE DEMOCRATIC

SOCIALIST REPUBLIC OF

SRI LANKA

NATIONAL MEDICINES REGULATORY

AUTHORITY ACT, No. 5 OF 2015

[Certified on 19th March, 2015]

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National Medicines Regulatory Authority 1

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 :-

1. This Act may be cited as the National Short title and

date of

Medicines Regulatory Authority Act, No. 5 of operation.

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)

2 National Medicines Regulatory Authority

Act, No. 5 of 2015

CHAPTER I

NATIONAL MEDICINES REGULATORY

AUTHORITY

PART I

ESTABLISHMENT OF THE AUTHORITY

Establishment of 2. (1) There shall be established an authority called the

the National National Medicines Regulatory Authority (hereinafter

Medicines

Regulatory referred to as the ‘Authority’).

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 3. The objects of the Authority shall be to –

Authority.

(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;

National Medicines Regulatory Authority 3

Act, No. 5 of 2015

(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.

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

the Authority.

(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;

4 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 5. (1) The Minister shall, in consultation with the

Authority.

Authority appoint one of the appointed members to be the

Chairman of the Authority.

National Medicines Regulatory Authority 5

Act, No. 5 of 2015

(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.

6. (1) The Minister shall, prior to appointing a person Conflict of

as a member of the Authority, satisfy himself that such person interests of the

has no financial or other conflict of interest in the affairs of members.

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

6 National Medicines Regulatory Authority

Act, No. 5 of 2015

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 7. A person shall be disqualified from being appointed

to be a member. 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;

National Medicines Regulatory Authority 7

Act, No. 5 of 2015

(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.

8. Every ex-officio member of the Authority shall hold Ex-officio

office so long as such officer holds office by virtue of which members.

such officer has been appointed to the Authority.

9. (1) Every appointed member of the Authority shall, Provisions

unless such officer vacates office earlier by death, resignation relating to

appointed

or removal, hold office for a period of three years, and shall members.

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.

8 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 10. (1) The Chairman shall preside at every meeting of

Authority.

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.

National Medicines Regulatory Authority 9

Act, No. 5 of 2015

(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.

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

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.

10 National Medicines Regulatory Authority

Act, No. 5 of 2015

(3) The Authority shall maintain a register of documents

to which the seal of the Authority has been affixed.

Authority to 12. (a) The Authority may invite experts on a relevant

invite experts to

subject matter to meetings of the Authority for the purpose

meetings.

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 13. The members of the Authority and the experts may

for attending

be paid such remuneration for attendance at meetings of the

meetings of the

Authority. Authority, as may be determined by the Minister with the

concurrence of the Minister assigned the subject of Finance.

Powers and 14. The powers and functions of the Authority shall be

functions of to :-

theAuthority.

(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;

National Medicines Regulatory Authority 11

Act, No. 5 of 2015

(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;

12 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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.

National Medicines Regulatory Authority 13

Act, No. 5 of 2015

PART II

APPOINTMENT OF CHIEF EXECUTIVE OFFICER AND STAFF OF THE

AUTHORITY

15. (1) The Authority shall in consultation with the Appointment of

Minister, appoint to the Staff of the Authority a Chief the Chief

Executive

Executive Officer (hereinafter referred to as the “CEO”) from Officer of the

among persons who hold a postgraduate degree from a Authority.

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

14 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 16. (1) The Authority may appoint such technical and

Authority. 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.

National Medicines Regulatory Authority 15

Act, No. 5 of 2015

(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.

17. (1) At the request of the Authority any officer in the Public officers

public service may, with the consent of that officer and the to be appointed

to the Staff of

Secretary to the Ministry under which that officer is

the Authority.

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

16 National Medicines Regulatory Authority

Act, No. 5 of 2015

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

Authority.

(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.

National Medicines Regulatory Authority 17

Act, No. 5 of 2015

(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.

19. The Authority may open and maintain any account Authority to

with any bank as it may think appropriate, and such account maintain

accounts.

shall be operated in accordance with prevailing financial

regulations of the Government pertaining to financial

transactions of public corporations.

20. (1) The financial year of the Authority shall be the Financial year

calendar year. and audit of

accounts.

(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.

21. Moneys belonging to the Authority may, with the Investment of

approval of the Minister and with the concurrence of the funds.

Minister assigned the subject of Finance, be invested in

Government approved securities.

22. (1) The Authority may, with the written consent of Borrowing

the Minister and the Minister assigned the subject of Finance powers of the

Authority.

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.

18 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 24. Every member of the Authority and all officers and

secrecy. 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.

National Medicines Regulatory Authority 19

Act, No. 5 of 2015

25. (1) The Authority may in writing and subject to Delegation of

such conditions as may be specified therein, delegate to the powers of the

Authority.

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.

26. (1) The Minister may from time to time, issue to the Directions by

Authority such general or special directions in writing as to the Minister.

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.

27. The CEO and the officers and employees of the Officers and

Authority shall be deemed to be public officers within the employees of

the Authority

meaning of and for the purposes of the Penal Code . deemed to be

public officers.

28. The Authority shall be deemed to be a Scheduled Authority

Institution within the meaning and for the purposes of the deemed to be a

Scheduled

Bribery Act and the provisions of that Act shall be construed

institution.

accordingly.

29. (1) Any expenses incurred by the Authority in any Expenses in suit

suit or prosecution brought by or against it before any Court, or prosecution

to be paid out of

shall be paid out of the Fund of the Authority and any costs

the Fund.

paid to or recovered by the Authority in any such suit or

prosecution shall be credited to the Fund of the Authority.

20 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 30. (1) There shall be established a National Advisory

National Committee, the main function of which shall be to advise

Advisory

Committee and the Minister and the Authority on matters pertaining to

divisions. 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;

National Medicines Regulatory Authority 21

Act, No. 5 of 2015

(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;

22 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 31. (1) The National Advisory Committee shall consist

the National of the following members appointed by the Minister -

Advisory

Committee.

(a) the Director General of Health Services;

National Medicines Regulatory Authority 23

Act, No. 5 of 2015

(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;

24 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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

National Medicines Regulatory Authority 25

Act, No. 5 of 2015

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.

32. (1) The Minister shall appoint any member of the Chairman &c.,

of the National

National Advisory Committee as the Chairman of the

Advisory

National Advisory Committee. 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.

33. The members of the National Advisory Committee, Remuneration of

the members of

shall not receive any remuneration for being in the National

the National

Advisory Committee, except an honorarium which may be Advisory

given for attending at the meetings of the National Advisory Committee.

Committee.

34. (a) The Authority shall appoint such number of Appointment of

officers,

officers employees and advisors as may be necessary for the employees &c.

proper discharge of the functions of the National Advisory

Committee.

26 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 35. The functions of the National Advisory Committee

National

shall be -

Advisory

Committee.

(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 37. The provisions of sections 5, 6, 7, 8, 9, 10, 11, 12

certain

and 13 of this Act shall mutatis mutandis apply to and in

provisions of

this Act in relation to the Chairman, members and the conducting of

relation to the affairs of the National Advisory Committee.

National

Advisory

Committee. PART III

NATIONAL MEDICINES QUALITY ASSURANCE LABORATORY

Establishment of 38. (1) For the purpose of this Act there shall be a

the National

Medicines Division to be known as the National Medicines Quality

Quality Assurance Laboratory (hereinafter referred to as the

Assurance

“NMQAL”).

Laboratory.

National Medicines Regulatory Authority 27

Act, No. 5 of 2015

(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.

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

NMQAL.

(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;

28 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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.

National Medicines Regulatory Authority 29

Act, No. 5 of 2015

CHAPTER III

REGULATION AND CONTROL OF ALL ASPECTS

PERTAINING TO MEDICINES

PART I

MEDICINES REGULATORY DIVISION

41. (1) The Medicines Regulatory Division established Medicines

under section 30(2) shall hereinafter in this Act be referred Regulatory

Division.

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.

42. (a) The principal function of the MR Division shall Functions of the

be to co-ordinate and assist the Authority to regulate and MR Division.

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

30 National Medicines Regulatory Authority

Act, No. 5 of 2015

(v) provisions of administrative assistance to

the Medicines Evaluation Committee

appointed under section 43 of this Act.

PART II

MEDICINES EVALUATION

Medicines 43. (1) There shall be appointed for the purposes of

Evaluation this Act, a Committee which shall be known as the

Committee.

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 44. (1) The MEC shall consist of the following persons

the MEC. 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;

National Medicines Regulatory Authority 31

Act, No. 5 of 2015

(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.

45. (1) The Authority shall appoint a Panel of Experts, Panel of

comprising of eminent professionals of medicine and other Experts.

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.

32 National Medicines Regulatory Authority

Act, No. 5 of 2015

Declaration of 46. Every member of the MR Division and the MEC

secrecy.

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 47. (1) The Authority shall issue general guidelines to

give general

guidelines for the MEC for the evaluation of medicines and other related

the evaluation. 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.

National Medicines Regulatory Authority 33

Act, No. 5 of 2015

(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.

48. The provisions of sections 5, 6, 7, 8, 9, 10, 11, 12 Application of

certain

and 13 of this Act shall mutatis mutandis apply to and in

provisions of

respect of the Chairman, members and the conducting of the this Act in

affairs of the MEC. relation to

MEC.

PART III

OFFENCES PERTAINING TO MEDICINE

49. (1) No person shall import, distribute, exhibit or Regulation of

sell any medicine that- manufacture,

importation, sale

and distribution

(a) is manufactured, prepared, preserved, packaged or of medicine.

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.

34 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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, 50. (1) Where the standard is prescribed for any

&c.,to be in medicine, no person shall label, package, sell, exhibit,

conformity with distribute or advertise any medicine which does not conform

the prescribed

to such standard or in such manner as is likely to be mistaken

standards.

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.

National Medicines Regulatory Authority 35

Act, No. 5 of 2015

(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).

51. No person shall sell, exhibit or distribute any Sale of

medicine as may be prescribed unless the premises in prescribed

medicine is

which the medicine was manufactured and the process prohibited

and conditions of manufacture of that medicine have unless premises

been approved in the prescribed form and manner as being and process of

manufacture

suitable to ensure that the medicine will be safe for use.

have been

approved.

52. No person shall sell, exhibit or distribute any Sale of

medicine as may be prescribed unless the batch from which prescribed

medicine

that medicine was taken has been approved in the prescribed prohibited

form and manner as reliable for use. unless the batch

from which such

medicine is

taken approved

as reliable.

53. No person shall manufacture, import, store, sell, Sale &c., of

re-pack, distribute, transport, exhibit or have in his prohibited

medicine.

possession any medicine which is prescribed as not safe

for use.

Possession of

54. No person other than the persons as may be prohibited

permitted by regulations shall obtain or have in his medicine.

possession any medicine restricted or prohibited by

regulations.

55. (1) No person shall advertise or promote Advertising,

any medicine without prior written approval of the Authority. importation,

sale and

distribution

(2) No person shall advertise or promote any medicine of medicine

as treatment

to the general public as a treatment, prevention or cure for

for

any of the prescribed diseases, disorders or abnormal prescribed

physical states. diseases

prohibited.

36 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 56. (1) Every Medical Practitioner, Dentist or Veterinary

a medicine to be Surgeon shall write the generic name of the medicine in

written in the

prescription. 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 57. Any person who contravenes any of the provisions

of the provisions specified in this Part of this Act commits an offence.

of this Part to be

an offence.

National Medicines Regulatory Authority 37

Act, No. 5 of 2015

PART IV

REGISTRATION AND LICENSING OF MEDICINES

58. (1) No person shall manufacture or import any Requirement to

medicine without registering such medicine with the register &c., of

Authority and obtaining a licence from the Authority medicines.

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.

59. (1) Any person who intends to manufacture or import Application for

any medicine shall make an application for the registration Registration of a

medicine.

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

38 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 60. (1) (a) The Authority may where necessary, call for

medicines. clarifications from the MEC, NMQAL or any other expert,

with regard to the reports submitted by the MEC and the

NMQAL.

National Medicines Regulatory Authority 39

Act, No. 5 of 2015

(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.

61. Where the Authority refuses the registration of the Refusal of

medicine, such refusal shall be communicated to the Registration.

applicant with reasons therefor within the stipulated time

period and shall inform the public of such refusal by order

published in the Gazette.

62. (1) (a) The Authority shall on registration of any Issuing of

medicine, issue a Certificate of Registration to the applicant certificate of

registration.

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.

40 National Medicines Regulatory Authority

Act, No. 5 of 2015

Issuing of 63. (1) The Authority may upon issuing the Certificate

licence. 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 65. (1) Where the Authority is of the opinion that –

suspension of

registration and

(a) the holder of certificate has failed to comply with

licence.

any condition subject to which any medicine has

been registered;

National Medicines Regulatory Authority 41

Act, No. 5 of 2015

(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.

42 National Medicines Regulatory Authority

Act, No. 5 of 2015

CHAPTER IV

REGULATION AND CONTROL OF ALL ASPECTS

PERTAINING TO MEDICAL DEVICES

PART I

MEDICAL DEVICES REGULATORY DIVISION

Medical Devices 66. (1) The Medical Devices Regulatory Division

Regulatory

established under section 30(2) shall hereinafter in this Act

Division.

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 67. (a) The principal function of the MDR Division

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.

National Medicines Regulatory Authority 43

Act, No. 5 of 2015

PART II

MEDICAL DEVICES EVALUATION

68. (1) There shall be appointed for the purposes of this Medical Devices

Act a Committee which shall be known as the Medical Evaluation

Committee.

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.

69. (1) The MDEC shall consist of the following persons Constitution of

who shall be appointed by the Authority- the MDEC.

(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);

44 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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;

National Medicines Regulatory Authority 45

Act, No. 5 of 2015

(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.

70. (1) The Authority shall appoint a Panel of Experts, Panel of

comprising of eminent professionals specialized in medical Experts.

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.

71. Every member of the MDR Division and the MDEC Declaration of

secrecy.

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

46 National Medicines Regulatory Authority

Act, No. 5 of 2015

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 72. (1) The Authority shall issue general guidelines to

give general the MDEC for the evaluation of medical devices and other

guidelines for

the evaluation. 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;

National Medicines Regulatory Authority 47

Act, No. 5 of 2015

73. The provisions of sections 5, 6, 7, 8, 9, 10, 11, 12 Application of

certain

and 13 of this Act shall mutatis mutandis apply to and in

provisions of

relation to the Chairman, members and the conducting of this Act in

the affairs of the MDEC. relation to

MDEC.

PART III

OFFENCES PERTAINING TO THE MEDICAL DEVICES

74. (1) The Authority shall list from time to time the Prohibition of

medical devices registered under this Act. importation &c.,

of medical

devices other

(2) No person shall import, sell, transport, distribute or than the listed.

advertise any medical device, other than a medical device

listed under subsection (1).

75. (1) No person shall manufacture, prepare, store, Regulation of

preserve, package or re-pack any medical device without manufacture,

importation, sale

adhering to Good Manufacturing Practices (GMP) and any and distribution

other prescribed guidelines or conditions. 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, Prohibition of

transport, sell or distribute any medical device that may manufacturing,

importation,

cause any injury to the health of the user when that medical

assembling, sale

device is used— and distribution

&c., of medical

(a) under conditions that are customary or usual in the devices.

use of the medical device; or

(b) according to the directions on the label

accompanying that medical device.

48 National Medicines Regulatory Authority

Act, No. 5 of 2015

Labeling, 77. No person shall label, package, treat, process, sell,

packaging and

assemble, distribute or advertise any medical device in a

advertising of

medical device. manner that is false, misleading, deceptive or likely to create

an erroneous impression regarding its safety and efficacy.

Prescribed 78. Where a standard is prescribed for any medical device,

standards of a no person shall label, package, sell, distribute or advertise

medical device

any medical device which does not conform to that standard

to be

maintained. or in such a manner as is likely to be mistaken for the medical

device for which the standard has been prescribed.

Advertising, 79. (1) No person shall advertise or promote any medical

importation, sale device without prior written approval of the Authority.

and distribution

of medical

(2) No person shall advertise or promote any medical

devices as a

treatment for device to the general public as a treatment, prevention or

prescribed cure for any of the prescribed diseases, disorders or abnormal

diseases physical states.

prohibited.

(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 80. No person other than the persons as may be permitted

prohibited

by regulations shall obtain or have in his possession any medical

medical devices.

device as may be restricted or prohibited by regulations.

Contravention of 81. Any person who contravenes any of the provisions

the provisions of specified in this Part of this Act commits an offence.

this Part to be an

offence.

PART IV

REGISTRATION AND LICENSING OF MEDICAL DEVICES

Requirement to 82. (1) No person shall manufacture or import any

register &c., of medical device without registering such medical device with

medical devices.

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.

National Medicines Regulatory Authority 49

Act, No. 5 of 2015

(3) Any person who contravenes any of the provisions

specified in subsection (1) or (2) commits an offence.

83. (1) Any person who intends to manufacture or import Application for

any medical device shall make an application for the Registration of a

Medical device.

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;

50 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 84. (1) (a) The Authority may where necessary, call for

medical devices. 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 85. Where the Authority refuses the registration of the

Registration. 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.

National Medicines Regulatory Authority 51

Act, No. 5 of 2015

86. The provisions of sections 62, 63, 64 and 65 of this Application of

Act shall mutatis mutandis apply to and in relation to— the provisions of

sections 62, 63,

64 and 65.

(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

87. (1) The Borderline Products Regulatory Division Borderline

established under section 30(2) shall hereinafter in this Act Products

Regulatory

be referred to as the BPR Division.

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.

88. (a) The principal function of the BPR division shall Functions of the

be to co-ordinate and assist the Authority to regulate and BPR Division.

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;

52 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 89. (1) There shall be appointed for the purposes of this

Products

Act a Committee which shall be known as the Borderline

Evaluation

Committee. 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 90. (1) The BPEC shall consist of the following persons

the BPEC. 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;

National Medicines Regulatory Authority 53

Act, No. 5 of 2015

(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.

54 National Medicines Regulatory Authority

Act, No. 5 of 2015

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

three years.

Panel of 91. (1) The Authority shall appoint a Panel of Experts,

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 92. Every member of the BPR division and the BPEC

secrecy.

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 93. (1) The Authority shall issue general guidelines to

give general the BPEC for the evaluation of borderline products and other

guidelines for related items, submitted to the BPEC.

the evaluation.

(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.

National Medicines Regulatory Authority 55

Act, No. 5 of 2015

(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.

94. The provisions of sections 5, 6, 7, 8, 9, 10, 11, 12 Application of

and 13 of this Act shall mutatis mutandis apply to and in certain

provisions of

relation to the Chairman, members and the conducting of this Act in

the affairs of the BPEC. relation to

BPEC.

PART III

OFFENCES PERTAINING TO BORDERLINE PRODUCTS

95. (1) The Authority shall list from time to time the Prohibition of

borderline products registered under this Act. importation &c.,

of borderline

products other

(2) No person shall import, sell, transport, distribute or than listed.

advertise any borderline product, other than a borderline

product listed under subsection (1).

96. (1) No person shall import, distribute, re-pack or Regulation of

sell any borderline product which— manufacture,

importation, sale

and distribution

(a) is not manufactured, prepared, preserved, packaged of borderline

or stored under good manufacturing practices and products.

good storage practices;

56 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 97. Where a standard is prescribed for borderline

is prescribed for

product, no person shall label, package, distribute or sell

borderline

products. 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, 98. (1) No person shall advertise or promote or

importation, sale

distribute any borderline product without prior written

and distribution

of borderline approval of the Authority.

products for

prescribed (2) No person shall advertise or promote any borderline

diseases product to the public as a treatment, prevention or cure for

prohibited.

any of the prescribed diseases, disorders or abnormal physical

states.

National Medicines Regulatory Authority 57

Act, No. 5 of 2015

(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.

99. No person other than the persons as may be Possession of

prescribed by regulations shall obtain or have in his prohibited

borderline

possession any prohibited borderline product which is not

product.

safe for general use.

100. Any person who contravenes any of the provisions Contravention

of the

specified in this Part of this Act commits an offence. provisions of

this Part to be

an offence.

PART IV

REGISTRATION AND LICENSING OF BORDERLINE PRODUCTS

101. (1) No person shall manufacture or import any Requirement to

register &c., of

borderline product without registering such borderline

borderline

product with the Authority and obtaining a licence from the products.

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.

102. (1) Any person who wishes to import, sell, Application for

manufacture, prepare or distribute any borderline product Registration of a

borderline

shall make an application for the registration of that

product.

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.

58 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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

National Medicines Regulatory Authority 59

Act, No. 5 of 2015

(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.

103. (1) (a) The Authority may where necessary, call Registration of

for clarifications from the BPEC, NMQAL or any other borderline

products.

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.

104. Where the Authority refuses the registration of the Refusal of

borderline product, such refusal shall be informed to the Registration.

applicant with reasons therefor within the stipulated time

period and shall inform the public of such refusal by Order

published in the Gazette.

105. The provisions of sections 62, 63, 64 and 65 of Application of

this Act shall mutatis mutandis apply to and in relation to the provisions of

sections 62, 63,

the — 64 and 65.

(i) issuing of certificate of registration;

(ii) issuing of licence;

60 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 106. (1) No person shall store, re-pack, assemble,

dishonest transport, distribute or sell any illegal, counterfeit or

dealings.

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 107. (1) The Authority shall, decide the residual shelf-

decide residual life of every medicine, medical device or borderline product

shelf-life of

medicines &c. imported into Sri Lanka at the port of entry.

National Medicines Regulatory Authority 61

Act, No. 5 of 2015

(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.

108. (1) The Authority shall, where the Authority finds Ban or

that any medicine, medical device or borderline product withdrawal

&c.,from, use of

does not meet the required standard or that the medicine,

medicine &c.

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.

109. (1) The Authority may grant permission in special Emergency and

other special

circumstances such as to save a life, to control an outbreak

circumstances.

of an infection or an epidemic or any other national

62 National Medicines Regulatory Authority

Act, No. 5 of 2015

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 110. (1) (a) No person shall distribute any medicine,

distribution of medical device or borderline product marked as Physician’s

samples of

sample to the general public.

medicine &c., to

be prohibited.

(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.

National Medicines Regulatory Authority 63

Act, No. 5 of 2015

111. (1) Subject to the provisions of subsection (3) no Permission to

person shall import or accept as a donation any medicine, import and to

accept as a

medical device or borderline product for free distribution or

donation of any

to promote within Sri Lanka, without the approval of the medicine &c.

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.

112. (1) The provisions of sections 58, 82 and 101 shall Importation &c.,

not apply to any patient who needs for his personal of medicines

&c., for

medication a medicine, medical device or borderline product

personal use.

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.

113. (1) No person shall manufacture, prepare, store or Licensing of

sell any medicine, medical device or borderline product in premises for

manufacturing

any premises unless such premises has been licensed in that &c., of medicine

regard by the Authority. &c.

(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.

64 National Medicines Regulatory Authority

Act, No. 5 of 2015

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

pertaining to

licence. (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 115. (1) The Authority shall establish for the purpose

the of this Act a Division to be known as Manufacturing

Manufacturing

Regulatory Division.

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.

National Medicines Regulatory Authority 65

Act, No. 5 of 2015

116. (1) The principal function of the Manufacturing Functions of the

Manufacturing

Regulatory Division shall be the regulation of manufacturing

Regulatory

of medicines, medical devices and borderline products in Division.

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.

117. Minister may make regulations to give effect to Regulations.

all or any of the provisions of this Part of this Act.

PART III

PRICING OF MEDICINES, MEDICAL DEVICES AND BORDERLINE

PRODUCTS

118. (1) (a) The Authority shall appoint a Committee Pricing of

to be known as the Pricing Committee. medicines &c.

(b) The composition, powers and functions of the Pricing

Committee shall be as prescribed.

66 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 119. (1) No person shall carry on a Pharmacy without

carry on a obtaining a licence from the Authority.

Pharmacy to

obtain a licence.

(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.

National Medicines Regulatory Authority 67

Act, No. 5 of 2015

(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.

120. (1) Every person who carries on a Pharmacy shall Requirement to

comply with Good Pharmacy Practices and other guidelines comply with

Good Pharmacy

and conditions prescribed by the Authority.

Practices.

(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.

68 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 123. (1) The Minister shall appoint an Appeals

Committee.

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.

National Medicines Regulatory Authority 69

Act, No. 5 of 2015

(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

124. (1) The Minister may appoint any Provincial Authorized

Director of Health Services, any Regional Director of Health Officers.

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.

70 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 125. (1) An Authorized Officer, for the performance of

Authorized his duties and the exercise of his powers under the Act may-

Officers.

(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

National Medicines Regulatory Authority 71

Act, No. 5 of 2015

(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.

72 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 126. (1) Upon the receipt of any information under

respect of section 125 (9) where the Authority is satisfied that there

articles and

vehicles seized. 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

National Medicines Regulatory Authority 73

Act, No. 5 of 2015

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.

127. (1) Where a sample obtained by an Authorized Authorized

Officer is required to be divided by him into parts, one of Officer to

produce before

which shall be retained by him and the part retained by him

court the part of

shall be produced in court at the commencement of the trial the sample

of the prosecution in relation to such sample. retained by him.

(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.

128. A copy made or extract taken from any book, Copy or extract

document or record by an Authorized Officer under section of document

taken by an

125(1) (d) shall, if certified to be a true copy or extract by the Authorized

Authorized Officer, be admissible in evidence against the Officer.

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.

74 National Medicines Regulatory Authority

Act, No. 5 of 2015

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 130. Every person who—

offences.

(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

National Medicines Regulatory Authority 75

Act, No. 5 of 2015

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.

131. (1) Every person who contravenes any of the Punishment for

provisions of this Act or any regulation made thereunder the

contravention of

shall be guilty of an offence and shall on conviction be the provisions of

liable— this Act.

(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

76 National Medicines Regulatory Authority

Act, No. 5 of 2015

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,

National Medicines Regulatory Authority 77

Act, No. 5 of 2015

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.

132. Every person who commits an offence under this Person

Act or any regulation made thereunder may be arrested committing

offence to be

without a warrant and every offence under this Act or arrested without

regulations made thereunder shall be triable by a magistrate a warrant and to

Court. be tried by a

Magistrate’s

Court.

133. (1) Where a person (hereinafter referred to as “the Where the

accused”) is charged with an offence under this Act, he shall, accused proves

that some other

upon complaint duly made by him in accordance with the

person is guilty

provisions of section 136 of the Code of Criminal Procedure of the offence.

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.

78 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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.

National Medicines Regulatory Authority 79

Act, No. 5 of 2015

135. (1) For the purposes of this Act and of any Presumptions.

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.

80 National Medicines Regulatory Authority

Act, No. 5 of 2015

Offence 136. Where an offence under this Act or any regulation

committed by made thereunder is committed by a body of persons and-

body of persons.

(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 137. (1) For the purposes of this Act and the regulations

Analyst. 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

National Medicines Regulatory Authority 81

Act, No. 5 of 2015

(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.

138. (1) In the absence of evidence to the contrary, a Report or

document purporting to be a report or a certificate signed by certificate of the

Approved

the Approved Analyst or an Additional Approved Analyst Analyst or an

upon any matter submitted to him for analysis or examination Additional

shall be sufficient evidence of the facts stated therein. Approved

Analyst.

(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.

139. Every Court shall give priority to the trial of any Priority for trial

person charged with, or indicted for, any offence under this and appeal

under this Act.

Act and to the hearing of any appeal from the conviction of

any such offence and sentence imposed on such conviction.

140. (1) The provisions of this Act and any regulation Application of

made thereunder relating to medicine which are excisable other written

laws.

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

82 National Medicines Regulatory Authority

Act, No. 5 of 2015

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;

National Medicines Regulatory Authority 83

Act, No. 5 of 2015

(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;

84 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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;

National Medicines Regulatory Authority 85

Act, No. 5 of 2015

(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.

86 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 143. (1) A prosecution for an offence under this Act or

proceedings. 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, 144. Cosmetics, Devices and Drugs Act, No. 27 of 1980

No. 27 of 1980.

is hereby repealed.

National Medicines Regulatory Authority 87

Act, No. 5 of 2015

145. Notwithstanding the repeal of Cosmetics, Devices Transitional

and Drugs Act, No. 27 of 1980 (hereinafter referred to as provisions.

“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

88 National Medicines Regulatory Authority

Act, No. 5 of 2015

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

National Medicines Regulatory Authority 89

Act, No. 5 of 2015

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

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

“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

90 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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 AUC0-t and

Cmax 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;

National Medicines Regulatory Authority 91

Act, No. 5 of 2015

(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;

92 National Medicines Regulatory Authority

Act, No. 5 of 2015

“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;

National Medicines Regulatory Authority 93

Act, No. 5 of 2015

“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;

94 National Medicines Regulatory Authority

Act, No. 5 of 2015

(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;

National Medicines Regulatory Authority 95

Act, No. 5 of 2015

(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;

96 National Medicines Regulatory Authority

Act, No. 5 of 2015

“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 147. In the event of an inconsistency between the

inconsistency Sinhala and Tamil texts of this Act, the Sinhala text shall

the Sinhala text

shall prevail. prevail.

National Medicines Regulatory Authority 97

Act, No. 5 of 2015

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