

**THE MEDICINES AND ALLIED SUBSTANCES BILL, 2013**

**MEMORANDUM**



The objects of this Bill are to—

- (a) continue the existence of the Pharmaceutical Regulatory Authority and re-name it as the Zambia Medicines Regulatory Authority;
- (b) provide for the functions and powers of the Authority;
- (c) provide for the registration and regulation of pharmacies, health shops and agro-veterinary shops;
- (d) provide for the registration and regulation of medicines and allied substances;
- (e) provide for the regulation of the manufacture, importation, exportation, possession, storage, distribution, supply, promotion, advertising, sale and use of medicines and allied substances;
- (f) provide for the regulation and control of clinical trials;
- (g) repeal and replace the Pharmaceutical Act, 2004; and
- (h) provide for matters connected with, or incidental to, the foregoing.

M. MALILA,  
*Attorney-General*

THE MEDICINES AND ALLIED SUBSTANCES  
BILL, 2013

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# A BILL

ENTITLED

**An Act to continue the existence of the Pharmaceutical Regulatory Authority and re-name it as the Zambia Medicines Regulatory Authority; provide for the functions and powers of the Authority; provide for the registration and regulation of pharmacies, health shops and agro-veterinary shops; provide for the registration and regulation of medicines and allied substances; provide for the regulation of the manufacture, importation, exportation, possession, storage, distribution, supply, promotion, advertising, sale and use of medicines and allied substances; provide for the regulation and control of clinical trials; repeal and replace the Pharmaceutical Act, 2004; and provide for matters connected with, or incidental to, the foregoing.**

ENACTED by the Parliament of Zambia.

Enactment

## PART I PRELIMINARY

1. This Act may be cited as the Medicines and Allied  
5 Substances Act, 2013. Short title

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

“administer” means to give a substance to a human being or animal orally, by injection or by introduction into the body in any other way or by external application, whether by direct contact with the body or not;

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“adulterated medicine” means any medicine—

(a) consisting in whole or in part of any filthy, putrid, decomposed, deleterious or foreign substance;

(b) that is prepared or stored under unsanitary conditions;

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(c) whose container is composed of any poisons or deleterious substance;

(d) that contains a colouring agent that is not prescribed;  
or

(e) that contains any harmful or toxic substance;

	“agro-veterinary shop” means a place or premises permitted to sell prescribed veterinary medicinal products and allied substances under the control of a relevant veterinary professional as determined by the Authority;	
	“allied substances” include cosmetics, disinfectants, food supplements, feed additives and supplements, medical and surgical sundries, medical devices and condoms;	5
Act No. 27 of 2010	“animal” has the meaning assigned to it in the Animal Health Act, 2010;	
Act No. 45 of 2010	“animal health facility” has the meaning assigned to it in the Veterinary and Veterinary Para-Professions Act, 2010;	10
	“assemble” in relation to a medicine, means enclosing the medicine or allied substance of the same description in a container before the medicine or allied substance is sold or supplied;	15
	“Authority” means the Zambia Medicines Regulatory Authority provided for under section three;	
	“biological product” includes vaccine, immune sera, anti-toxin, anti-venom, toxoid, blood and blood components, allergy products used in the prevention, treatment or cure of disease or condition in human beings and animals synthesised from living organisms or other product;	20
	“Board” means the Board of the Authority constituted under section seven;	
	“certificate of registration” means the certificate of registration of a pharmacy;	25
	“Chairperson” means the person appointed as Chairperson of the Board under section seven;	
	“clinical trial” means the systematic study involving human participants or animal subjects that serves to answer the efficacy of a medicine, biological products or method of prevention or treatment;	30
	“committee” means a committee of the Board established under section ten;	
	“cosmetic” means any substance manufactured or sold for use in cleansing, beautifying or altering the hair, eyes, teeth or nails, or complexion of the skin, and includes deodorants and perfumes;	35
	“counterfeit medicine or allied substance” means a medicine or allied substance which is deliberately or fraudulently mislabeled or misrepresented with respect to identity or source, or a medicine or allied substance which—	40

- (a) has wrong ingredients;  
(b) contains active ingredients or not;  
(c) has insufficient or excess active ingredients; or  
(d) has fake packaging;
- 5 “deal” means to sell or offer for sale or trade by wholesale;  
“dental surgeon” means a person registered as such under  
the Health Professions Act, 2009; Act No. 24 of  
2009  
“Director General” means the person appointed as Director  
General under section *twelve*;
- 10 “dispense” means to count, measure or decant a medicine  
from a bulk supply or to prepare, mix, dissolve or supply a  
medicine for the treatment of a person or animal, but does  
not include the administration of medicine;  
“distribute” means the division and movement of  
15 pharmaceutical products from the premises of the  
manufacturer of the products or from another central point  
or to an intermediate point or to the end user by means of  
any method of transport;  
“Expert Advisory Committee” means the Expert Advisory  
20 Committee established under section *nine*;  
“former Authority” means the Pharmaceutical Regulatory  
Authority established under the repealed Act; Act No. 14 of  
2004  
“health facility” has the meaning assigned to it in the Health  
25 Professions Act, 2009; Act No. 24 of  
2009  
“health shop” means a place or premises permitted to sell a  
prescribed list of medicine by the Authority, under the  
control of an authorised person as determined by the  
Authority;
- 30 “hospital” has the meaning assigned to it in the Health  
Professions Act, 2009; Act No. 24 of  
2009  
“hospital pharmacy” means a pharmacy which is part of a  
health facility;  
“ingredient” in relation to the manufacture or preparation of  
35 a substance, includes anything which is the sole active or  
inactive ingredient of that substance;  
“inspector” means a person appointed as an inspector under  
section *fifty-five*;  
“label” means to affix to, or otherwise display on, a container  
40 or package, a notice describing the ingredients and contents  
thereof;  
“Laboratory” means the National Drug Quality Control  
Laboratory established under section *fifty-four*;

“manufacture” in relation to a medicine or allied substance, includes any process carried out in the course of making that medicine or allied substance, but does not include the process of—

(a) dissolving or dispensing a product in, or diluting or mixing it with, some other substance for purposes of administering it; or

(b) the incorporation of a medicine in any animal feed;

“marketing authorisation” means the authorisation granted, under section *thirty-nine*, for the placement of a medicine or allied substance on the market;

“medical device” includes an instrument, apparatus, component, part or accessory manufactured or sold for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptoms of the disease, or abnormal physical state in human beings or animals;

Act No. 24  
of 2009

“medical doctor” means a person registered as a medical doctor under the Health Professions Act, 2009;

“medicine” means human medicine, veterinary medicine, medicinal product, herbal medicine or any substance or mixture of substances for human or veterinary use intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person or animal;

“medicinal product” means any substance or combination of substances which may be administered to human beings or animals in order to make a medical diagnosis or to restore, correct or modify the physiological functions in human beings or animals;

“member” means a person appointed as a member of the Board under section *seven*;

Act No. 31  
of 1997

“midwife” means a person registered as a midwife under the Nurses and Midwives Act, 1997;

Act No. 31 of  
1997

“nurse” means a person registered as a nurse under the Nurses and Midwives Act, 1997;

“package” means anything in or by which any medicine, herbal medicine, therapeutic substance or allied substance is enclosed, covered or contained, and includes primary and secondary packaging;

- “ pharmaceutical licence ” means the licence issued, under section *thirty-four*, to a person to manufacture, distribute or deal in a medicine or allied substance; Act No. 24 of 2009
- 5 “ pharmacist ” means a person registered as a pharmacist under the Health Professions Act, 2009;
- “ pharmacy ” means a drugstore, druggist, chemist or any business or premises registered as such under section *sixteen*;
- 10 “ prescription ” means a written direction given by an authorised prescriber directing that a stated amount of a medicine specified in the direction be dispensed for the person or animal named in the direction;
- “ prescription only medicine ” means a medicine dispensed only on prescription;
- 15 “ Register ” means, in relation to—
- (a) pharmacies, health shops and agro-veterinary shops, the Register provided for under section *thirty-one*;
  - (b) licences and permits, the Register of Licences and Permits provided for under section *thirty-eight*;
  - 20 (c) marketing authorisation, the Register of Marketing Authorisations provided for under section *forty-eight*; and
  - (d) clinical trial certificates, the Register of Clinical Trial Certificates provided for under section *fifty-three*;
- 25 “ repealed Act ” means the Pharmaceutical Act, 2004; Act No. 14 of 2004
- “ sell ” means to offer for sale, expose for sale, have in possession for sale, and supply, whether the supply is made for consideration or not;
- 30 “ substance ” means any natural or artificial material, whether in the form of solid, liquid, gas, vapour or any active or inactive substance or pharmaceutical ingredient;
- “ sub-standard medicine ” means a product whose composition and ingredients do not meet the approved quality specifications and which may be consequently ineffective and often dangerous to the patient;
- 35 “ veterinary surgeon ” means a person registered as a veterinary surgeon under the Veterinary and Veterinary Para-Professions Act, 2010; and Act No. 45 of 2010
- 40 “ Vice-Chairperson ” means the person elected as Vice-Chairperson under section *seven*.

PART II

THE ZAMBIA MEDICINES REGULATORY AUTHORITY

- Continuation and re-naming of Pharmaceutical Regulatory Authority Act No. 14 of 2004
3. (1) The Pharmaceutical Regulatory Authority established under the repealed Act shall continue to exist as if established under this Act and is hereby renamed the Zambia Medicines Regulatory Authority. 5
- (2) The Authority shall be a body corporate with perpetual succession and a common seal, capable of suing and of being sued in its corporate name, and with power, subject to the provisions of this Act, to do all such acts and things as a body corporate may, by law, do or perform. 10
- (3) The provisions of the First Schedule apply to the Authority.
- Seal of Authority
4. (1) The seal of the Authority shall be such device as may be determined by the Authority and shall be kept by the Director-General. 15
- (2) The affixing of the seal shall be authenticated by the Chairperson or the Vice Chairperson and the Director-General or any other person authorised in that behalf by a resolution of the Board.
- (3) Any contract or instrument which if entered into or executed by a person not being a body corporate, would not be required to be under seal, may be entered into or executed without seal on behalf of the Authority by the Director-General or any other person generally or specifically authorised by the Board in that behalf. 20
- (4) Any document purporting to be a document under the seal of the Authority or issued on behalf of the Authority shall be received in evidence and shall be deemed to be so executed or issued, as the case may be, without further proof, unless the contrary is proved. 25
- Functions of Authority
5. The functions of the Authority are to—
- (a) grant pharmaceutical licences and marketing authorisations; 30
- (b) inspect any premises used for the purpose of manufacturing, distribution, sale, importation or exportation of medicines or allied substances or for any other purposes regulated under this Act; 35
- (c) regulate and control the manufacture, importation, exportation, distribution and sale of medicines and allied substances;
- (d) regulate and control the advertising and promotion of medicines and allied substances; 40

- (e) register and regulate pharmacies, health shops and agro-veterinary shops;
- 5 (f) in consultation with the relevant professional bodies, establish, maintain and develop standards for the operation of pharmacies, health shops and agro-veterinary shops;
- (g) serve and protect the public interest in all matters relating to the sale of medicines and allied substances;
- 10 (h) regulate and monitor the conduct of clinical trials;
- (i) establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines and allied substances;
- (j) conduct post-marketing surveillance;
- 15 (k) establish, maintain and enforce standards for drug quality control laboratories;
- (l) advise the Minister on policies relating to the regulation and control of medicines and allied substances;
- (m) collaborate with corresponding medicines regulatory authorities in other countries;
- 20 (n) in consultation with relevant research institutions, determine national priorities in pharmaceutical research; and
- (o) do all such things as are connected with, or incidental to, the functions of the Authority under this Act.

25 6. The Authority may—

- (a) direct any pharmacy, health shop or agro-veterinary shop or any person providing services relating to the manufacture, importation, exportation, distribution and sale of medicines and allied substances to deliver the services in such manner as to ensure compliance with this Act;
- 30 (b) require any pharmacy, health shop or agro-veterinary shop, manufacturer, wholesale dealer, distributor, importer, exporter or person to submit such information and records as may be necessary to enable the Authority to monitor the performance of the pharmacy, health shop, agro-veterinary shop, manufacturer, wholesale dealer, distributor, importer or exporter;
- 35 (c) consider any matter relating to the manufacture, importation, exportation, distribution and sale of medicines and allied substances and make representations thereon to the Minister;
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Powers of Authority

(d) declare certain substances as medicine; and

(e) determine the method of sale of medicines.

Constitution  
of Board of  
Authority

7. (1) There is hereby constituted a Board of the Authority which shall consist of the following

part time members appointed by the Minister:

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(a) a representative of the Pharmaceutical Society of Zambia;

(b) a representative of the Medical Association of Zambia;

(c) a representative of the Health Professions Council of Zambia;

(d) a representative of the department of pharmacy of a higher education institution;

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(e) a representative of the School of Veterinary Medicine of a higher education institution;

(f) a representative of the pharmaceutical industry;

(g) a representative of the Ministry responsible for health;

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(h) a representative of the Ministry responsible for commerce;

(i) a representative of the Ministry responsible for veterinary services;

(j) community development;

(k) a representative of the Veterinary Association of Zambia;

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(l) a representative of the Attorney- General; and

(m) two other persons.

(2) The members referred to in subsection (1) shall be recommended by their respective institutions.

(3) The Minister shall appoint the Chairperson of the Board from amongst the members.

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(4) The members shall elect the Vice Chairperson of the Board from amongst themselves.

(5) A person shall not be nominated or appointed as a member of the Board if the person—

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(a) is an undischarged bankrupt;

(b) has been convicted of an offence involving fraud or dishonesty;

(c) has been convicted of an offence under any written law and sentenced to imprisonment for a period exceeding six months without the option of a fine;

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- (d) has been found guilty of professional misconduct; or  
(e) is an employee of the Authority.

8. The Board shall, subject to the provisions of this Act, perform the following functions: Functions of Board

- 5 (a) review the policy and strategic plan of the Authority;  
(b) oversee the implementation and successful operation of the policy and functions of the Authority;  
(c) approve the annual budget and plans of the Authority;  
(d) monitor and evaluate the performance of the Authority  
10 against budgets and plans;  
(e) establish and issue guidelines and standards for purposes of this Act;  
(f) establish and approve rules and procedures for the appointment, discipline, termination and terms and  
15 conditions of service of the staff of the Authority;  
(g) make recommendations to the Minister for amendments to this Act or the issuance of regulations under this Act; and  
(h) perform any other function conferred or imposed on the  
20 Board by, or under, this Act.

9. (1) The Board shall constitute an Expert Advisory Committee which shall consist of experts in human medicine, veterinary medicine and allied substances. Expert Advisory Committee

(2) The Expert Advisory Committee constituted under subsection 25 (1) shall—

- (a) advise the Board on—  
(i) licensing of medicines and allied substances;  
(ii) monitoring the advertisements on medicines and allied substances;  
30 (iii) monitoring the standards relating to medicines and allied substances; and  
(iv) monitoring the conduct of clinical trials;  
(b) provide technical and scientific advice on any aspect of medicines and allied substances;  
35 (c) review risk assessment and risk management measures relating to medicines and allied substances;  
(d) recommend containment measures, reporting mechanisms, remedial measures monitoring procedures and other appropriate conditions for medicines or allied substances;

- (e) make policy recommendations to the Board; and
- (f) perform any other function conferred on the Expert Advisory Committee by the Board for purposes of this Act.

(3) Subject to any specific or general directive of the Board, the Expert Advisory Committee may regulate its own procedure. 5

(4) The members of the Expert Advisory Committee shall elect a Chairperson and Vice-Chairperson from among themselves.

(5) The Minister may, by statutory instrument, make regulations to provide for the composition, tenure and procedure of the Expert Advisory Committee. 10

Committees

10. (1) The Board may, for the purpose of performing its functions under this Act, constitute such committees as it considers necessary and may delegate to the committee such of its functions as it considers fit. 15

(2) The Board may appoint as members of a committee, persons who are, or are not, members of the Board, except that at least one member of a committee shall be a member of the Board.

(3) A person serving as a member of a committee shall hold office for such period as the Board may determine. 20

(4) Subject to any specific or general direction of the Board, a committee may regulate its own procedure.

Delegation of functions of Board

11. Subject to this Act, the Board may, by direction, in writing, and subject to any terms and conditions as it considers necessary, delegate to the Director-General any of its functions under this Act. 25

Director General

12. (1) The Board shall, with the approval of the Minister, appoint a Director General on such terms and conditions as it may determine.

(2) The Director-General shall be the chief executive officer of the Authority and shall, subject to the control of the Board, be responsible for the day-to-day administration of the Authority. 30

(3) A person shall not be appointed as Director General unless the person is a pharmacist.

(4) The Director General may attend meetings of the Board and of any committee and may address such meetings, but shall have no vote. 35

(5) The Director General shall be the Secretary to the Board.

(6) The Board may, whenever the Director-General is for any reason unable to discharge the functions of the Director-General's office, appoint an acting Director-General to discharge the Director-General's functions.

(7) The Board may appoint on such terms and conditions as it may determine, such other staff of the Authority as it considers necessary for the performance of its functions under this Act.

10 13. An action or other proceeding shall not lie or be instituted against the Director-General or a member of staff of the Authority for, or in respect of, any act or thing done in good faith in the exercise of, or performance of or purported exercise of, or performance of, any of the powers, functions or duties conferred under this Act. Immunity

### PART III

#### 15 REGISTRATION AND REGULATION OF PHARMACIES, HEALTH SHOPS AND AGRO-VETERINARY SHOPS

14. (1) A person shall not—

20 (a) operate, either on that person's own behalf or on behalf of another person, a pharmacy that is not registered under this Act or a health shop or agro-veterinary shop without a permit issued by the Authority; Prohibition of operation of unregistered pharmacy, health shop or agro-veterinary shop

25 (b) assume, take, exhibit or in any way make use of any title, emblem, description or addition reasonably calculated to suggest that a pharmacy is registered, or the health shop or agro-veterinary shop has a permit.

(2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding three million penalty units or to imprisonment for a period not exceeding five years, or to both.

30 15. (1) A person who intends to operate a pharmacy shall apply to the Authority for a certificate of registration in the prescribed manner and form upon payment of the prescribed fee. Application for certificate of registration

(2) A separate application shall be made in respect of each premises to be operated as a pharmacy.

35 (3) The Authority may—

(a) request an applicant to furnish any other information in relation to an application, within such period as it may determine; and

(b) inspect the premises in respect of which an application is made before the issuance of the certificate of registration.

Issue of certificate of registration

16. (1) The Authority shall, within sixty days of receipt of an application made under section *fifteen*, issue the applicant with a certificate of registration if—

- (a) the application meets the requirements of this Act;
- (b) the premises to be used are suitable for conducting pharmacy business;
- (c) the pharmacy is under the management and control of a registered pharmacist at all times; and
- (d) the activity or business to be carried out does not contravene any other written law.

(2) Where a person applies for a certificate of registration under section *fifteen* and the certificate is not granted within sixty days of the filing of the application, the certificate shall be deemed to have been granted.

(3) Subject to the other provisions of this Act, a certificate of registration issued under this section shall be subject to such terms and conditions as the Authority may determine.

Rejection of application

17. (1) The Authority shall reject an application for a certificate of registration if—

- (a) the activity or business to be carried out contravenes any law in force;
- (b) the premises in respect of which the application is made are not suitable for pharmacy business and do not comply with prescribed standards of pharmacy practice;
- (c) the certificate of registration previously held by the applicant was cancelled by the Authority; or
- (d) the applicant submits false information in relation to the application.

(2) The Authority shall, where it rejects an application under subsection (1), inform the applicant, in writing, and give the reasons for the rejection.

Display of certificate of registration

18. A holder of a certificate of registration shall display the certificate in a conspicuous manner and place at the place of business.

19. (1) A holder of a certificate of registration shall submit to the Authority an annual return or no-change return in the prescribed manner and form upon payment of the prescribed fee.

Annual return

(2) A holder of a certificate of registration shall, where the status of a pharmacy required to file a return under this section has not changed, file a no-change return indicating the financial year in which the return is filed and containing a general statement that there has been no change in any given particulars in the return from the filing of the previous return.

(3) Notwithstanding the filing of a no-change return, the Director-General may cause to be inspected any records of the person which the Director-General considers necessary for the better carrying out of this Act.

(4) A person who fails to submit an annual return or a no-change return on, or before, the prescribed date is liable to pay the Authority a fine of ten thousand penalty units and a further fine of two thousand eight hundred penalty units for each day during which the default continues.

20. (1) Where the holder of a certificate of registration decides not to continue with the business to which the certificate relates, the holder shall notify the Authority, in writing, and shall agree with the Authority on the terms and conditions of the surrender of the certificate.

Surrender of  
certificate of  
registration

(2) Where a certificate of registration is surrendered under subsection (1), the certificate shall lapse and subject to section *twenty-three*, be cancelled.

21. (1) A certificate of registration shall not be transferred to a third party without the prior approval of the Authority.

Transfer of  
certificate  
of  
registration

(2) An application for approval to transfer a certificate of registration shall be made to the Authority in the prescribed manner and form.

(3) The Authority may, within fourteen days of receipt of an application to transfer a certificate of registration, determine the application in accordance with this Act.

22. (1) A holder of a certificate of registration shall, where a change is made or occurs in any of the following registered particulars:

Amendment  
of certificate  
of  
registration

- (a) the business name;
- (b) the physical address of the pharmacy;
- (c) the structure of the place of business; or
- (d) the name of the pharmacist designated as the manager of the pharmacy;

notify the Authority, in the prescribed manner and form, within fourteen days of the change.

(2) The Authority shall, upon receipt of the notice referred to in subsection (1), amend the certificate of registration accordingly. 10

(3) The Authority shall, where it identifies an error on the Register relating to any particulars of a certificate of registration, inform the holder of the certificate and amend the certificate accordingly.

(4) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding two thousand eight hundred penalty units for each day during which the default continues. 15

23. (1) Subject to the other provisions of this Act, the Authority may suspend or cancel a certificate of registration if— 20

Suspension  
or  
cancellation  
of certificate  
of  
registration

- (a) the holder obtained the certificate by fraud or deliberate or negligent submission of false information or statements;
- (b) the holder operates the pharmacy under unsanitary conditions; 25
- (c) the pharmacist or responsible person obtains medicines and allied substances from unauthorised suppliers or deals in unauthorised products;
- (d) the pharmacy in respect of which it was issued is not compliant with prescribed standards of pharmacy practice or is not managed or controlled by a registered pharmacist or authorised person determined by the Authority; 30
- (e) the pharmacist fails to maintain the required records on medicines and allied substances; 35
- (f) the holder fails to submit an annual return in accordance with this Act; or
- (g) the holder contravenes the terms and conditions of the certificate of registration, this Act or any other relevant law. 40

(2) The Authority shall, before suspending or cancelling a certificate of registration in accordance with subsection (1), give written notice to the holder thereof of its intention to suspend or cancel the certificate and shall give the reasons for the intended  
5 suspension or cancellation and require the holder to show cause, within a period of not more than thirty days, why the certificate should not be suspended or cancelled.

(3) The Authority shall not suspend or cancel a certificate of registration under this section if the holder takes remedial measures  
10 to the satisfaction of the Authority within the period referred to in subsection (2).

(4) Where a holder who is notified under subsection (2) fails to show cause to the satisfaction of the Authority, or does not take any remedial measures to the satisfaction of the Authority within  
15 the time specified in that subsection, the Authority shall suspend or cancel the certificate of registration.

(5) Where a certificate of registration is cancelled, the holder of the certificate shall return it to the Authority and the Authority shall cancel the name and the particulars relating to the pharmacy from  
20 the Register.

(6) Subject to subsection (7), a person whose certificate of registration is cancelled may re-apply for registration in the prescribed manner and form, if that person takes remedial measures to the satisfaction of the Authority.

25 (7) An application for re-registration may be made after two years from the date of the cancellation of the registraton.

24. (1) The Authority may order the closure of a pharmacy Closure of pharmacy  
where—

- 30 (a) the pharmacy contravenes the terms and conditions of registration in a manner that presents danger or imminent harm to members of the public;
- (b) the pharmacy is not registered under this Act; or
- (c) the pharmacy contravenes the provisions of this Act or any other relevant law.

(2) The Authority shall, where it receives an inspection report indicating that a pharmacy is not compliant with the requirements of this Act or its certificate of registration, or is offering services in excess of those permitted to the pharmacy, give the pharmacy written notice of the violation. 5

(3) A pharmacy shall, where it receives a notice under subsection (2), within fourteen days of service of the notice, provide the Director-General with a written plan of correction of the violation, indicating a schedule of dates by which corrective action shall be taken. 10

(4) A pharmacy shall, where the plan of correction submitted by the pharmacy under subsection (3) is accepted by the Director-General, meet the schedule contained in the plan.

(5) The Authority shall, where the plan of correction submitted by a pharmacy is rejected by the Director-General, revoke the certificate of registration and order the closure of the pharmacy. 15

Loss of certificate of registration

25. (1) A holder of a certificate of registration who loses the certificate may apply to the Authority for a duplicate certificate of registration in the prescribed manner and form upon payment of the prescribed fee. 20

(2) The Authority shall, within fourteen days of the receipt of an application under subsection (1), issue a duplicate certificate of registration if the applicant meets the requirements of this Act.

Management of hospital pharmacies

26. (1) Subject to subsection (2), a hospital pharmacy shall be managed by a pharmacist. 25

(2) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for circumstances under which a hospital pharmacy may be operated by a pharmacy technologist or such other person as the Authority may determine, under the supervision of a pharmacist. 30

Act No. 24 of 2009

(3) In this section, "pharmacy technologist" means a person registered as a pharmacy technologist under the Health Professions Act, 2009.

Standards of pharmacy practice

27. For the purposes of this Part, the Minister may, on the recommendation of the Authority, by statutory instrument, provide for standards for the practice of pharmacy in pharmacies and hospital pharmacies. 35

28. (1) The Authority may, upon application by a person, issue a dispensing certificate to the person to dispense medicines and allied substances to patients under their care in a health facility.

Dispensing  
certificate

(2) A person who dispenses any medicine or allied substance without a dispensing certificate to a patient in a health facility commits an offence and is liable, upon conviction, to a fine not exceeding two million penalty units or to imprisonment for a period not exceeding four years, or to both.

(3) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for—

- (a) the criteria and procedure for applying for a dispensing certificate and the grant, amendment, renewal, transfer and revocation of a dispensing certificate;
- 15 (b) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of a dispensing certificate;
- (c) the exemption of certain categories of persons from any provision of this section; and
- 20 (d) any other matters that are necessary or incidental to the effective regulation of dispensing certificates under this Act.

29. (1) The Authority may, upon application by a person, issue an agro-veterinary shop permit to the person to sell a prescribed list of veterinary medicinal products, under the control and management of such persons as the Authority may authorise.

Agro-  
veterinary  
shop permit

(2) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for—

- 30 (a) the criteria and procedure for applying for an agro-veterinary shop permit and the grant, amendment, renewal, transfer and revocation of an agro-veterinary shop permit;
- (b) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of an agro-veterinary shop permit; and
- 35 (c) any other matters that are necessary or incidental to the effective regulation of agro-veterinary shop permits under this Act.

Health shop  
permit

30. (1) The Authority may, upon application by a person, issue a health shop permit to the person to handle a prescribed list of medicines and allied substances in designated areas under the control and management of such persons as the Authority may authorise.

(2) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for—

(a) the criteria and procedure for applying for a health shop permit and the grant, amendment, renewal, transfer and revocation of a health shop permit;

(b) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of a health shop permit; and

(c) any other matters that are necessary or incidental to the effective regulation of health shop permits under this Act.

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Register of  
Pharmacies,  
Agro-  
Veterinary  
Shops and  
Health Shops

31. (1) The Authority shall keep and maintain a Register of the pharmacies, agro-veterinary shops and health shops registered under this Act in which shall be entered the names and other details relating to the pharmacies, agro-veterinary shops and health shops.

(2) The Register referred to in subsection (1) shall be kept at the offices of the Authority and shall be open to inspection by the public at such times and on such conditions, including the payment of a fee for inspection, as the Board may determine.

(3) A person may, upon payment of the prescribed fee, require a copy of the certificate of registration, dispensing certificate or permit of any person or a copy or extract of any other particulars from the Register to be certified by the Director-General.

(4) Any document purporting to be an extract or copy of any entry in the Register and duly certified to be a true copy or extract under the hand of the Director-General shall be received in evidence as to the matters stated therein in any legal proceedings.

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Publication of  
registered  
pharmacies,  
agro-  
veterinary  
shops and  
health shops

32. The Authority shall publish, annually, the names of all the pharmacies, agro-veterinary shops and health shops registered under this Act in a daily newspaper of general circulation in Zambia.

## PART IV

## LICENCES, IMPORT AND EXPORT PERMITS

33. (1) A person shall not manufacture, distribute or deal in any medicine or allied substance without a pharmaceutical licence. Prohibition of manufacture, distribution, etc. of medicine or allied substance without pharmaceutical licence
- 5 (2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding two million penalty units or to imprisonment for a period not exceeding four years, or to both.
- 10 34. (1) A person who intends to manufacture, distribute or deal in any medicine or allied substance shall apply to the Authority for a pharmaceutical licence in the prescribed manner and form upon payment of the prescribed fee. Pharmaceutical licence
- (2) The Authority shall, within ninety days of the receipt of an application under subsection (1), issue a pharmaceutical licence to the applicant if the applicant meets the requirements of this Act.
- (3) The Authority shall reject an application which does not meet the requirements of this Act and inform the applicant of the reasons for the rejection.
- 20 (4) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for—
- (a) the criteria for the licensing of persons under subsection (1);
- 25 (b) the procedure for applying for a pharmaceutical licence and the grant, amendment, renewal, transfer and revocation of a pharmaceutical licence;
- (c) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of a pharmaceutical licence; and
- 30 (d) such other matters as are necessary or incidental to the effective regulation of licences under this Part.
- (5) The Minister may, on the recommendation of the Authority, and for the purposes of facilitating the effective implementation and enforcement of this Act—
- 35 (a) exempt certain categories of persons from the application of some or all of the provisions of this section; and
- (b) provide that some or all of the provisions of this section shall not apply in certain circumstances.
- 40 35. (1) A person shall not import any medicine or allied substance without an import permit. Import permit

(2) This section does not apply to any medicine or allied substance imported by a traveller entering Zambia for the traveller's use as may be prescribed.

(3) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding one million 5 penalty units or to imprisonment for a period not exceeding three years, or to both.

(4) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for—

- (a) the criteria for the regulation of persons under subsection 10 (1);
- (b) the procedure for applying for an import permit and the grant, amendment, renewal, transfer, suspension and revocation of an import permit;
- (c) the terms and conditions attaching to an application, grant, 15 amendment, refusal, renewal, transfer, suspension or revocation of an import permit; and
- (d) such other matters as are necessary or incidental to the effective regulation of import permits under this Part.

Export permit 36. (1) A person shall not export any medicine or allied substance 20 without an export permit.

(2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding one million 25 penalty units or to imprisonment for a period not exceeding three years, or to both.

(3) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for—

- (a) the criteria for the regulation of persons under subsection (1);
- (b) the procedure for applying for an export permit and the 30 grant, amendment, renewal, transfer, suspension and revocation of an export permit;
- (c) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer, suspension or 35 revocation of an export permit; and
- (d) such other matters as are necessary or incidental to the effective regulation of export permits under this Part.

37. Where a person intends to import or export a narcotic drug, psychotropic substance or precursor for medical or scientific use, the person shall—
- 5 (a) in addition to obtaining an import or export permit, obtain additional authorisation from the Authority; and
- (b) comply with additional requirements as may be provided for under the Dangerous Drugs Act and Narcotic Drugs and Psychotropic Substances Act and any other written law.
- 10 38. The Authority shall maintain a Register of Licences and Permits, in the prescribed form, which shall contain such particulars as the Authority may consider necessary for purposes of this Act.

Additional requirements for import or export of narcotic drugs, psychotropic substances and precursors .

Cap. 95

Cap. 96

Register of Licences and Permits

#### PART V

##### REGULATION OF MEDICINES AND ALLIED SUBSTANCES

- 15 39. (1) A person shall not place on the market, advertise, market, manufacture, sell, import, supply, administer or deal in any manner with any medicine or allied substance without a marketing authorisation issued by the Authority.
- (2) A person who intends to place on the market, advertise, 20 market, manufacture, sell, import, supply, administer or deal in any manner with any medicine or allied substance shall apply to the Authority for a marketing authorisation in the prescribed manner and form.
- (3) A person who contravenes subsection (1) commits an offence 25 and is liable, upon conviction, to a fine not exceeding two million penalty units or to imprisonment for a period not exceeding four years, or to both.
- (4) This section does not apply to—
- (a) donated medicines;
- 30 (b) a person importing medicine for that person's use or for the use of that person's relative, if the quantity of the imported medicine is based on the prescription;
- (c) a physician, dentist or veterinary surgeon importing 35 medicine on the physician's, dentist's or veterinary surgeon's order for administration to a person or animal, if the quantity of the imported medicine is based on a prescription;
- (d) medicine manufactured under the supervision of a pharmacist or by a pharmacist—

Marketing authorisation

- (i) for sale in the pharmacist's own pharmacy; or
- (ii) in a hospital for its use;
- (e) medicine imported or exported in response to a declared health emergency;
- (f) medicine imported by an authorised institution for 5 administration to patients under its care; and
- (g) any medicine or allied substance used for purposes of a clinical trial.

(5) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for— 10

- (a) the criteria for the regulation of persons under subsection (1);
- (b) the procedure for applying for a marketing authorisation and the grant, amendment, renewal, transfer and revocation of a marketing authorisation; 15
- (c) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of a marketing authorisation; and
- (d) such other matters as are necessary or incidental to the effective regulation of marketing authorisations under 20 this Part.

(7) A holder of a marketing authorisation shall pay such annual retention fee as the Minister may prescribe.

Categories of medicines

40. (1) The categories of medicines to which this Part applies are— 25

- (a) prescription only medicine;
- (b) pharmacy medicine; and
- (c) general sale medicine.

(2) Medicines shall be dispensed in accordance with the respective requirements applicable to the categories specified in 30 subsection (1) and as shall be prescribed by statutory instrument.

Medicines list

41. The Minister may, on the recommendation of the Authority, by statutory instrument, provide for a list of substances to be considered as medicines.

Prohibition of sale of prescription only medicines without prescription

42. (1) A person shall not sell or supply medicine which is 35 required to be sold by prescription only to any person without a prescription.

(2) For the purposes of this section, an authorised prescriber shall prescribe medicines which under this Act are required to be dispensed only under a prescription by issuing a prescription in the prescribed form.

5 (3) Unless otherwise provided, all prescriptions shall specify the medicine to be administered by reference to the generic name of that medicine.

(4) Subject to subsection (5), a prescription signed by an authorised prescriber authorising the sale or supply of a medicine shall not be dispensed on more than one occasion, except that if 10 the prescription expressly directs that it may be dispensed on a specified number of occasions or at specified intervals in a specific period, it may be dispensed in accordance with that direction.

(5) Notwithstanding subsection (4), insulin and medicines for 15 the treatment of asthma or other such diseases as the Minister may, on the advice of the Authority, by statutory instrument specify, may be sold or supplied any number of times under an initial prescription of a medical doctor or veterinary surgeon.

(6) In this section, “ authorised prescriber ” means a medical 20 doctor, a dental surgeon, a veterinary surgeon or such other person as the Minister may, on the advice of the Authority, by statutory instrument, designate.

(7) Where a generic medicine is prescribed under subsection 25 (3), a pharmacist or any person acting under the supervision of the pharmacist, or a veterinary surgeon to whom the prescription is presented, shall dispense the generic medicine specified in that prescription, unless such generic medicine is not available.

(8) A person who contravenes subsection (1) commits an offence 30 and is liable, upon conviction, to a fine not exceeding two million penalty units.

(9) The Minister may, for the purpose of preventing the improper use of prescription only medicines, on the recommendation of the Authority, by statutory instrument—

35 (a) provide for the control of the importation, exportation, sale, possession, distribution, use and labelling of prescription only medicines;

(b) exclude any prescription only medicine or preparation of such medicine from the operation of this Part;

40 (c) prohibit, regulate or restrict the manufacture of prescription only medicine; and

(d) regulate the use by any medical doctor, dental surgeon or veterinary surgeon of preparations containing a prescription only medicine and the dispensing of the preparations.

- Labelling of medicines 43. Medicines shall be labelled in such manner as the Minister may, on the recommendation of the Authority, provide by statutory instrument.
- Sale of medicine 44. (1) A person shall not sell by retail or otherwise supply medicine in a place other than a pharmacy, health facility or an animal health facility, except with the written approval of the Authority. 5
- (2) Any medicine sold in a place other than a pharmacy, health facility or animal health facility shall be sold in the original package labelled by the manufacturer with— 10
- (a) full instructions for use;
  - (b) indications, contra indications, warnings and precautions; and
  - (c) any other information as the Minister may provide, by statutory instrument, on the recommendation of the Authority. 15
- (3) A medical doctor or dental surgeon shall not sell any medicine to any person unless it is in a package for an individual patient's use only.
- (4) A wholesaler, manufacturer or importer shall not sell any medicine to any person unless that person is duly authorised to handle medicines and allied substances under this Act. 20
- Advertising of medicines or allied substances 45. (1) An advertisement of any medicine or allied substance shall conform to the information relating to the medicine or allied substance approved by the Authority and as specified in the marketing authorisation. 25
- (2) A medicine or allied substance which is sold by prescription only shall not be advertised to the general public without the prior written approval of the Authority.
- (3) In this section, "advertisement" means any representation by any means whatsoever for the purpose of promoting, directly or indirectly, the sale or disposal of any medicine or allied substance. 30
- (4) A person who contravenes subsection (1) or (2) commits an offence and is liable, upon conviction, to a fine not exceeding one million penalty units or to imprisonment for a period not exceeding three years, or to both. 35
- (5) Where a person has been charged with an offence under this section, it shall be a defence for that person to prove—

(a) that the person's business is to publish or arrange for the publication of advertisements;

5 (b) that the advertisement was received in the ordinary course of business and the person charged had no reason to suspect that its publication would amount to an offence under this Act; and

(c) that the advertisement was commissioned by a third party.

46. (1) The Authority may, where it determines that it is not in the public interest that any medicine or allied substance should be made available to the public, by notice, in writing, served on any person or in the *Gazette*, direct that person to return the medicine or allied substance which the person has in that person's possession to—

Recall of  
medicine,  
etc. from  
circulation

(a) the manufacturer of the medicine or allied substance;

15 (b) in the case of any imported medicine or allied substance, to the importer concerned; or

(c) deliver it or send it to the Authority or such other person as the Authority may designate.

(2) The Authority may, by notice, in writing, direct the manufacturer or importer of the medicine or allied substance referred to in subsection (1) or the person referred to in paragraph (c) of subsection (1), who has in their possession any quantity of the medicine or allied substance, including the returned quantity to deal with or dispose of that quantity in such manner as the Authority may determine.

(3) A person shall not sell any medicine or allied substance which is the subject of a notice under subsection (1).

(4) A person who contravenes subsection (3) commits an offence and is liable, upon conviction, to a fine not exceeding one million penalty units or to imprisonment for a period not exceeding three years, or to both.

47. The Minister may, on the recommendation of the Authority, by statutory instrument, make regulations for monitoring the safety of medicines and allied substances.

Monitoring  
medicine and  
allied  
substance

35 48. (1) The Authority shall keep and maintain a Register of Marketing Authorisations issued under this Act.

Register of  
Marketing  
Authorisations

(2) The Register referred to in subsection (1) shall be kept at the offices of the Authority and shall be open to inspection by the public at such times and on such conditions, including the payment of a fee for inspection as the Board may determine.

PART VI

REGULATION OF CLINICAL TRIALS

Prohibition of conducting clinical trial without certificate	<p><b>49.</b> (1) A person shall not conduct a clinical trial involving a medicine or allied substance without a clinical trial certificate.</p> <p>(2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding three million penalty units or imprisonment for a period not exceeding five years, or to both.</p>	5
Application for clinical trial certificate	<p><b>50.</b> (1) A person who intends to conduct a clinical trial shall apply to the Authority for a clinical trial certificate in the prescribed manner and form upon payment of the prescribed fee.</p> <p>(2) The Authority shall reject an application for a clinical trial certificate if—</p> <p style="padding-left: 20px;">(a) the application does not meet the requirements of this Act;</p> <p style="padding-left: 20px;">(b) the activity to be carried out contravenes any law in force;</p> <p style="padding-left: 20px;">(c) the clinical trial certificate previously held by the applicant has been revoked by the Authority;</p> <p style="padding-left: 20px;">(d) the applicant submits false information in relation to the requirements for the application; or</p> <p style="padding-left: 20px;">(e) the premises to be used for the clinical trials is not suitable for the intended purpose.</p> <p>(3) The Authority shall, where it rejects an application under subsection (1), inform the applicant accordingly and give the reasons therefor.</p> <p>(4) The Minister may, on the recommendation of the Authority, by statutory instrument, provide for—</p> <p style="padding-left: 20px;">(a) the criteria for the regulation of persons under subsection (1);</p> <p style="padding-left: 20px;">(b) the procedure for applying for a clinical trial certificate and the grant, amendment, renewal, transfer and revocation of a clinical trial certificate;</p> <p style="padding-left: 20px;">(c) the terms and conditions attaching to an application, grant, amendment, refusal, renewal, transfer or revocation of a clinical trial certificate; and</p> <p style="padding-left: 20px;">(d) such other matters as are necessary or incidental to the effective regulation of clinical trials under this Part.</p>	10 15 20 25 30 35

51. (1) The Authority shall, within ninety days of receipt of an application under section *fifty*, issue the applicant with a clinical trial certificate if—

Grant of  
clinical trial  
certificate

- (a) the application meets the requirements of this Act;
- 5 (b) the clinical trial does not contravene any other written law;
- (c) appropriately qualified persons are available to handle the medicine or allied substance for purposes of the clinical trial; and
- 10 (d) the premises on which the applicant proposes to conduct the clinical trials are suitable for the intended purpose.
- (2) A certificate granted under this section shall be valid for such period as shall be specified in the certificate.

52. The Authority shall inspect clinical trial sites during the 15 course of the trial and at such intervals as it may determine.

Inspection of  
clinical trial  
sites

53. (1) The Authority shall keep and maintain a Register of Clinical Trial Certificates issued under this Act in which it shall enter the names and other details relating to clinical trials.

Register of  
Clinical Trial  
Certificates

(2) The Register referred to in subsection (1) shall be kept at 20 the offices of the Authority and shall be open to inspection by the public at such times and on such conditions, including the payment of a fee for inspection, as the Board may determine.

## PART VII

### THE NATIONAL DRUG QUALITY CONTROL LABORATORY

25 54. (1) There is hereby established the National Drug Quality Control Laboratory which shall be managed by the Authority and shall facilitate the regulation of medicines and allied substances under this Act.

National  
Drug Quality  
Control  
Laboratory

- (2) The Authority shall use the Laboratory to—
- 30 (a) verify the safety, quality and efficacy of medicines and allied substances which are manufactured or imported into the country by persons who are authorised or licenced under this Act;
- 35 (b) examine, analyse and conduct research on medicine and allied substances;
- (c) provide laboratory services to the general public;
- (d) provide practical training for personnel in the analysis of medicines and allied substances; and
- 40 (e) perform such other functions relating to the analysis of medicines and allied substances as it considers necessary.

(3) The Authority shall charge such fees for the analysis of medicines and services provided by the.

(4) The Board shall appoint a Director for the Laboratory on such terms and conditions as it may determine, who shall be responsible for the day-to-day administration of the Laboratory. 5

(5) The Board shall appoint such number of pharmaceutical analysts as it may consider necessary for purposes of performing its functions under this section.

(6) A pharmaceutical analyst shall, as soon as is practicable, analyse or examine medicines or allied substances sent to the laboratory and issue a certificate of analysis in such form as may be prescribed. 10

(7) The Authority may use any approved laboratory to verify the quality, efficacy and safety of medicines and allied substances and the laboratory shall, upon analysis or examination of the medicines or allied substances, issue a certificate of analysis. 15

(8) A certificate of analysis issued under this section shall be received in evidence and shall be deemed to be so issued as the case may be, without further proof, unless the contrary is proved.

PART VIII 20  
INSPECTIONS

Inspectors 55. (1) The Board may appoint any suitably qualified person to be an inspector for the purposes of ensuring compliance with this Act, on such terms and conditions as it may determine.

(2) The Authority shall provide an inspector with an identification card, in the prescribed form, which shall be *prima facie* evidence of the inspector's appointment as such. 25

(3) An inspector shall, in performing any function under this Act—

(a) be in possession of the identification card referred to in subsection (2); and 30

(b) show the identification card to any person who requests to see it or is subject to an inspection or investigation under this Act.

(4) An inspector may, for the purpose of enforcing the provisions of this Act, at any reasonable time, and on the authority of a warrant, enter any premises, pharmacy, health shop, agro-veterinary shop, container, vessel, vehicle, aircraft or other conveyance that the inspector has reasonable grounds to believe is used for the commission of an offence or purposes contrary to the provisions of this Act, and— 35 40

- 5 (a) search the pharmacy, health shop, agro-veterinary shop, container, vessel, vehicle, aircraft or other conveyance, or the premises of a manufacturer, importer, exporter, seller or distributor of any medicine or allied substance or any person licensed or regulated under this Act, including a private dwelling, where information or documents which may be relevant to an inspection may be kept or which are being used for the commission of an offence under this Act;
- 10 (b) search any person on the premises if the inspector has reasonable grounds to believe that the person has possession of an article, document, record, medicine or allied substance that has a bearing on an investigation, except that a person shall only be searched by a person of the same sex;
- 15 (c) examine any document, record, book, article, medicine or allied substance found on the premises that has a bearing on an inspection or investigation;
- 20 (d) require information to be given about any document, record, book, article, medicine or allied substance in any premises by—
- (i) the owner of the premises;
- (ii) the person in control of the premises;
- 25 (iii) any person who has control of the document, record, book, article, medicine or allied substance; or
- (iv) any other person who may have the information;
- 30 (e) seize any document, book, record, article, computer or other electronic storage device, medicine or allied substance that has a bearing on an inspection or investigation or is used for purposes contrary to the provisions of this Act;
- 35 (f) take samples of any medicine or allied substance as may be necessary for the purposes of testing, examination or analysis;
- (g) take extracts from, or make copies of, any book, record or document found on the premises that has a bearing on an inspection or investigation;
- 40 (h) use any computer system or any other electronic device on the premises, or require the assistance of any person on the premises to use that computer system or electronic device, to—

(i) search any data contained in, or available to the computer system or electronic device;

(ii) reproduce any record from the data; or

(iii) seize any output from the computer or electronic device for examination and copying; and 5

(i) attach and, if necessary, remove from the premises for examination and safeguarding any document, record, book or article that has a bearing on an inspection or investigation.

(5) An inspector who removes any document, book, record or 10 article from any premises under subsection (4) shall—

(a) issue a receipt for the document, book, record or article to the owner of, or person in control of, the premises; and

(b) return the document, book, record or article as soon as practicable after achieving the purpose for which it was 15 removed.

(6) A person who—

(a) delays, assaults, threatens or obstructs an inspector in the performance of the inspector's functions;

(b) refuses to give an inspector such reasonable assistance 20 as the inspector may require for the purpose of exercising the inspector's powers;

(c) gives an inspector false or misleading information in answer to an inquiry made by the inspector; or

(d) impersonates an inspector or presents oneself to be an 25 inspector;

commits an offence and is liable, upon conviction, to a fine not exceeding five hundred thousand penalty units or to imprisonment for a period not exceeding two years, or to both.

(7) An inspector shall furnish the Authority with a written report 30 and any other information relating to an inspection, as the Authority may require.

(8) Nothing in this section requires a person to disclose or produce information or a document, if the person would in an action in a court be entitled to refuse to disclose or produce the information or 35 document.

## PART IX

## GENERAL PROVISIONS

56. (1) A person aggrieved with a decision of the Authority may appeal to the Minister within thirty days from the date of service of the decision. Appeals

(2) The Minister shall make a decision on the appeal lodged under subsection (1) within ninety days of receiving the appeal.

(3) A person aggrieved with the decision of the Minister under subsection (2) may appeal to the High Court within thirty days from the date of service of the decision.

57. (1) Notwithstanding the provisions of the Patents Act or any other written law, where— Authority to manufacture patented medicine Cap. 400

(a) the Minister declares a national health emergency or state of extreme urgency;

15 (b) the public interest so requires; or

(c) any medicine or allied substance is required for public non-commercial use;

the Authority may authorise the manufacture locally, or importation, of a generic formulation of a medicine or allied substance, notwithstanding that a patent in respect of that medicine has been issued in Zambia.

(2) The Authority shall not grant authorisation to a person to the exclusion of the patent holder.

(3) The grant of an authorisation under subsection (1), shall be subject to review by a court.

58. (1) A person who fraudulently obtains a licence, permit, authorisation or registration under this Act or makes any false or misleading statement in connection with any medicine or allied substance commits an offence and is liable, upon conviction, to a fine not exceeding one million penalty units or to imprisonment for a period not exceeding three years, or to both. General offences

(2) A person who—

(a) deals in unregistered medicines or allied substances;

(b) tampers with any sample taken for purposes of this Act;

35 (c) obtains medicines or allied substances from unauthorised suppliers; or

(d) fails to maintain records for medicines or allied substances registered under this Act;

commits an offence and is liable, upon conviction, to a fine not exceeding four million penalty units or to imprisonment for a period not exceeding seven years, or to both.

(3) In addition to the penalty provided in subsection (1) and (2), the court before which a person is convicted of an offence under this section may order—

- (a) that any medicines or allied substances in respect of which the offence is committed be forfeited to the State and be disposed of as the court may determine;
- (b) that the costs for disposal of any medicine or allied substance be borne by the offender; or
- (c) the cancellation of any licence permit, certificate or authorisation issued to that person under this Act.

Prohibition of manufacture, import, export, etc. of sub-standard, counterfeit or adulterated medicines or allied substances

**59** (1) A person shall not manufacture, import, export, distribute, sell, store or deal in any manner with sub-standard, counterfeit, adulterated or misbranded medicines or allied substances. 15

(2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding two million penalty units or to imprisonment for a period not exceeding four years, or to both. 20

(3) In addition to the penalty provided in subsection (2), the court before which a person is convicted of an offence under this section may order that any medicines or allied substances in respect of which the offence is committed be forfeited to the State to be destroyed. 25

Prohibition of supply of expired medicines

**60.** (1) A person shall not supply or sell an expired medicine or allied substance.

(2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding one million penalty units or to imprisonment for a period not exceeding three years, or to both. 30

(3) In addition to the penalty provided for in subsection (2), the court before which a person is convicted of an offence under this section may order that the medicines or allied substances in respect of which the offence is committed be forfeited to the State to be destroyed. 35

Prohibition of deceptive acts

**61.** (1) A person shall not label, package, treat, process, sell or advertise any medicine or allied substance in a manner that is false, misleading or deceptive in respect of its character, constitution, value, potency, quality, composition, merit or safety or in contravention of any provision of this Act. 40

(2) A person who contravenes subsection (1) commits an offence and is liable, upon conviction, to a fine not exceeding one million penalty units or to imprisonment for a period not exceeding three years, or to both.

5    **62.** (1) A person shall not sell any cosmetic that—

(a) has in or upon it any substance that is likely to cause injury to the health of the user when the cosmetic is used—

10           (i) according to the direction on the label of, or accompanying, such cosmetic; or

(ii) for such purposes and by such methods of use as are customary or usual; or

15           (b) consists in whole or in part of any filthy, rotten, decomposed or diseased substance or of any injurious foreign matter.

(2) A person shall not manufacture, import, export, sell or supply any cosmetic that does not meet the prescribed standards of quality.

20 (3) A person who contravenes subsection (1) or (2) commits an offence and is liable, upon conviction, to a fine not exceeding one million penalty units or to imprisonment for a period not exceeding three years, or to both.

**63.** A person who sells, prepares, packages or stores for sale any cosmetic under insanitary conditions commits an offence.

25    **64.** Where a standard has been prescribed for a cosmetic, any person who labels, packages, sells or advertises any article in such a manner that it is likely to be mistaken for a cosmetic of the prescribed standard commits an offence, unless the article complies with the prescribed standard.

30    **65.** (1) A person shall not sell any medical device that may cause injury to the health of the user when the medical device is used—

(a) according to the direction on the label of, or accompanying, that medical device; or

35           (b) for such purposes and by such methods of use as are customary or usual.

Prohibition  
of  
manufacture,  
sale, etc of  
harmful  
cosmetics

Sale and  
preparation  
of cosmetics  
under  
insanitary  
conditions

Standards of  
cosmetics

Prohibition  
of sale of  
harmful  
medical  
devices

(2) A person shall not manufacture, import, sell or supply any medical device that does not meet the prescribed standards of quality.

(3) A person who contravenes subsection (1) or (2) commits an offence and is liable, upon conviction, to a fine not exceeding two million penalty units or to imprisonment for a period not exceeding 5 four years, or to both.

General penalty

**66.** A person who contravenes a provision of this Act for which a specific penalty is not provided for under this Act, commits an offence and is liable, upon conviction, to a fine not exceeding one million penalty units or to imprisonment for a period not exceeding 10 three years, or to both.

Offence by body corporate or unincorporate body

**67.** Where an offence under this Act is committed by a body corporate or an unincorporate body, every director or manager of the corporate or unincorporate body is liable, upon conviction, as if the director or manager had personally committed the offence, unless 15 the director or manager proves to the satisfaction of the court that the act constituting the offence was done without the knowledge, consent or connivance of the director or manager or that the director or manager took reasonable steps to prevent the commission of the offence. 20

Guidelines

**68.** (1) The Authority may make guidelines for the better carrying out of the provisions of this Act.

(2) The guidelines referred to in subsection (1) shall, upon publication in a daily newspaper of general circulation in Zambia, be binding on all persons regulated under this Act. 25

Regulations

**69.** (1) The Minister may, by statutory instrument, make regulations for the better carrying out of the provisions of this Act.

(2) Without prejudice to the generality of subsection (1), regulations under that subsection may make provision for—

(a) the prohibition, regulation or restriction of the manufacture 30 or importation of pharmaceutical preparations and prescription only medicines;

(b) the required standards for pharmacies, agro-veterinary shops and health shops, including their operation and the maintenance, space, equipment and facilities required 35 for pharmacies, agro-veterinary shops and health shops;

(c) the required standards for the manufacture, supply, dispensing and the distribution of medicines and allied substances;

- 5 (d) the compounding of prescriptions and the dispensing of medicines or allied substances by medical doctors, dental surgeons, veterinary surgeons and the conditions under which the compounding and dispensing of medicines may be earned out;
- (e) the records to be kept by pharmacies, health shops and agro-veterinary shops;
- (f) the advertising, promotion and labelling of medicines and allied substances;
- 10 (g) the recall or withdrawal of medicines and allied substances that do not meet the prescribed standards of quality, efficacy and safety;
- (h) the handling of donated medicines;
- (i) the disposal of obsolete, expired or unwanted medicines or allied substances, in consultation with the Zambia Environmental Management Agency;
- 15 (j) the storage and standards for medicines and allied substances;
- (k) the period for which any books or registers required to be kept for the purposes of this Act are to be preserved;
- 20 (l) the fees to be paid for certificates, permits, authorisations and licences under this Act;
- (m) the restriction of the number and location of entry points through which medicines, herbal medicines or allied substances may be imported or exported;
- 25 (n) the categorisation of methods of sale for medicines and allied substances; and
- (o) generally the carrying into effect of the purposes of this Act.

30 70. (1) The Pharmaceutical Act, 2004, is hereby repealed.

Repeal of Act  
No. 14 of 2004

(2) Notwithstanding subsection (1), the provisions of the Second Schedule apply in respect of the matters specified therein.

35 (3) Notwithstanding subsection (1), a person who immediately before the commencement of this Act held office as a member of the Board of the former Authority shall hold office as a member of the Board for a period of three months after which the Minister shall appoint the members of the Board in accordance with the provisions of this Act.

40 (4) Notwithstanding subsection (1), a licence or certificate issued under the repealed Act shall continue to be valid for six months, after which the holder of the licence or certificate shall apply for a licence, permit, authorisation or certificate in accordance with the provisions of this Act.

Act No. 14 of  
2004

FIRST SCHEDULE

(Section 3(3))

THE ZAMBIA MEDICINES REGULATORY AUTHORITY

PART I

ADMINISTRATION OF AUTHORITY

5

Tenure of office and vacancy

1. (1) Subject to the other provisions of this Act, a member of the Board shall hold office for a period of three years and may be re appointed for one further period of three years.

(2) A member may resign upon giving one month's notice, in writing, to the Minister. 10

(3) The office of a member shall become vacant—

(a) if the member is absent, without reasonable excuse, from three consecutive meetings of the Board of which the member has had notice;

(b) if the member is adjudged bankrupt; 15

(c) if the member is convicted of an offence under this Act or any other written law and sentenced to imprisonment for a period exceeding six months;

(d) if the member ceases to be a representative or member of the institution which recommended the member; 20

(e) if the member is found guilty of professional misconduct;

(f) if the member becomes mentally or physically incapable of performing the duties of a member; or

(g) upon the member's death.

(4) On the expiration of the period for which a member is appointed the member shall continue to hold office until a successor has been appointed but in no case shall the further period exceed four months.

Filling of casual vacancy

2. The Minister may, where the office of a member becomes vacant before the expiry of the term of office, appoint another member in place of the member who vacates office but that member shall hold office only for the unexpired part of the term. 30

Proceedings of Board

3. (1) Subject to the other provisions of this Act, the Board may regulate its own procedure.

(2) The Board shall meet for the transaction of business at least once in every three months at such places and times as the Board may determine. 35

(3) A meeting of the Board may be called by the Chairperson, upon giving notice of not less than fourteen days, and shall be called by the Chairperson if not less than one-third of the members so request in writing, except that if the urgency of any particular matter does not permit the giving of the notice, a special meeting may be called upon giving a shorter notice.

(5) The Chairperson, or in the absence of the Chairperson, the Vice-Chairperson, with six other members shall constitute a quorum at any meeting of the Board.

10 (6) There shall preside at any meeting of the Board—  
(a) the Chairperson;  
(b) in the absence of the Chairperson, the Vice Chairperson;  
and  
(c) in the absence of the Chairperson and the Vice  
15 Chairperson, such other member as the members present may elect for the purpose of that meeting.

(7) A decision of the Board on any question shall be by a majority of the members present and voting at the meeting and in the event of an equality of votes, the person presiding at the meeting shall  
20 have a casting vote in addition to that person's deliberative vote.

(8) The Board may invite any person, whose presence is in its opinion desirable, to attend and to participate in the deliberations of the meeting of the Board, but that person shall not have any vote.

25 (9) Where a member is for any reason unable to attend a meeting of the Board, the member may, in writing, nominate another person from the same organisation to attend the meeting in that member's stead and that person shall be deemed to be a member for the purpose of that meeting.

30 (10) The validity of any proceedings, acts or decisions of the Board shall not be affected by any vacancy in the membership of the Board or by any defect in the appointment of any member or by reason that any person not entitled to do so, took part in the proceedings.

35 4. There shall be paid to a member of the Board or a committee of the Board such allowances as the Minister may determine. Allowances of member

5. (1) If any person is present at a meeting of the Board or any committee of the Board at which any matter is the subject of consideration, and in which matter that person or that persons  
40 relative is directly or indirectly interested in a private capacity, that Disclosure of interest

person shall, as soon as is practicable after the commencement of the meeting, declare that interest and shall not, unless the Board or the committee otherwise directs, take part in any consideration or discussion of, or vote on, any question relating to that matter.

(2) A declaration of interest made under subparagraph (1) shall 5 be recorded in the minutes of the meeting at which it is made.

(3) In this paragraph, "relative" in relation to a person means—

(a) a parent, son, daughter, brother, sister, niece, uncle, auntie, grandparent or cousin of the person or that person's spouse; and 10

(b) a spouse of that person.

Prohibition of publication or disclosure of information to unauthorised persons

6. (1) A person shall not, without the consent in writing given by, or on behalf of, the Authority, publish or disclose to any unauthorised person, otherwise than in the course of duties of that person, the contents of any document, communication, or 15 information whatsoever, which relates to or which has come to the knowledge of that person in the course of that person's duties under this Act.

(2) A person who contravenes subparagraph (1) commits an offence and is liable, upon conviction, to a fine not exceeding five 20 hundred thousand penalty units or to imprisonment for a period not exceeding two years, or to both.

(3) A person who, having any information which to the knowledge of that person has been published or disclosed in contravention of subparagraph (1), unlawfully publishes or communicates the 25 information to any other person, commits an offence and is liable, upon conviction, to a fine not exceeding five hundred thousand penalty units or to imprisonment for a period not exceeding two years, or to both.

Immunity

7. An action or other proceeding shall not lie or be instituted 30 against a member of the Board or a member of a committee of the Board for, or in respect of, any act or thing done or omitted to be done in good faith in the exercise or performance of, or purported exercise or performance of any of the powers, functions or duties conferred under this Act. 35

## PART II FINANCIAL PROVISIONS

Funds of Authority

8. (1) The funds of the Authority shall consist of such moneys as may—

(a) be appropriated to the Authority by Parliament for the purposes of the Authority;

(b) be paid to the Authority by way of fees, grants or donations; and

5 (c) otherwise vest in or accrue to the Authority.

(2) The Authority may, subject to the approval of the Minister—

(a) accept moneys by way of grants or donations from any source within or outside Zambia; and

10 (b) raise by way of loans or otherwise, such moneys as it may require for the discharge of its functions.

(3) There shall be paid from the funds of the Authority—

(a) the salaries, allowances, loans, gratuities and pensions of members of staff of the Authority;

15 (b) such reasonable travelling and other allowances for the members of the Board and of any committee of the Board when engaged on the business of the Authority, at such rates as the Minister may determine; and

(c) any other expenses incurred by the Authority in the performance of its functions under this Act.

20 (4) The Authority may, subject to the approval of the Minister, invest in such manner as it considers appropriate such funds of the Authority which it does not immediately require for the discharge of its functions.

25 9. The financial year of the Authority shall be a period of twelve months ending on 31st December in each year.

Financial year

10. (1) The Authority shall cause to be kept proper books of account and other records relating to its accounts.

Accounts and audit

(2) The Authority shall, within ninety days of expiry of financial year, submit to the Minister a report concerning its activities during the financial year.

30 (3) The report referred to in subparagraph (2) shall include statements of income and expenditure and a statement of affairs or balance sheet.

(4) The accounts of the Authority shall be audited annually or whenever necessary by the Auditor-General.

35 11. (1) As soon as practicable, but not later than six months after the end of the financial year, the Authority shall submit to the Minister a report concerning its activities during that financial year.

Annual report

(2) The report referred to in subparagraph (1) shall include information on the financial affairs of the Authority and there shall be appended to that report—

- (a) an audited balance sheet;
- (b) an audited statement of income and expenditure; and 5
- (c) such other information as the Minister may require.

(3) The Minister shall, not later than seven days after the first sitting of the National Assembly next after receipt of the report referred to in subparagraph (1), lay the report before the National Assembly. 10

SECOND SCHEDULE  
(Section 68(2))

SAVINGS AND TRANSITIONAL PROVISIONS

Staff of Authority

1. (1) For the avoidance of doubt, a person who, before the commencement of this Act, was an officer or employee of the former Authority, shall continue to be an officer or employee of the Authority, as the case may be, as if appointed or employed under this Act. 15

(2) The service of the persons referred to in subparagraph (1) shall be treated as continuous service. 20

(3) Nothing in this Act affects the rights and liabilities of any person employed or appointed by the former Authority before the commencement of this Act.

Transfer of assets and liabilities

2. (1) On or after the commencement of this Act, there shall be transferred to, vest in and subsist against the Authority by virtue of this Act and without further assurance, all assets, rights and obligations which immediately before that date were the assets, rights, liabilities and obligations of the former Authority. 25

(2) Subject to sub-paragraph (1), every deed, bond and agreement, other than an agreement for personnel service, to which the former Authority was a party immediately before the commencement of this Act whether or not of such a nature that rights, liabilities and obligations could be assigned, shall, unless its subject matter or terms make it impossible that it should have effect as modified, as provided under this paragraph, have effect as if— 30 35

- (a) the Authority had been party to it;
- (b) for any reference to the former Authority there was substituted, with respect to anything required to be done on or after the commencement of this Act, a reference to the Authority; or 40

(c) for any reference to any officer of the former Authority, not being a party to it and beneficially interested, there were substituted, with respect to anything required to be done on or after the commencement of this Act, a  
5 reference to such officer of the Authority as it shall designate.

(3) Where under this Act, any assets, rights, liabilities and obligations of the former Authority are deemed to be transferred to the Authority in respect of which transfer a written law provides  
10 for registration, the Authority shall make an application, in writing, to the appropriate registration authority for registration of the transfer.

(4) The registration authority, referred to in subparagraph (2), shall make such entries in the appropriate register as shall give  
15 effect to the transfer and, where applicable, issue to the transferee concerned a certificate of title in respect of the property or make necessary amendments to the register and shall endorse the deeds relating to the title, right or obligation concerned and no registration fees or other duties shall be payable in respect of the transaction.

20 3. (1) Any legal proceedings or application of the former Authority pending immediately before the commencement of this Act by or against the former Authority may be continued by or against the Authority.

Legal  
proceedings

(2) After the commencement of this Act, proceedings in  
25 respect of any right, liability or obligation which was vested in, held, enjoyed, incurred or suffered by the former Authority, may be instituted by or against the Authority.