Chapter 15:03 MEDICINES AND ALLIED SUBSTANCES CONTROL ACT

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Acts 14/1969, 1/1996, 6/2000, 22/2001, 23/2004 5/2014 and GLA2015.

SI 161/2012

ARRANGEMENT OF SECTIONS

AN ACT to establish a Medicines Control Authority of Zimbabwe and to confer functions on such Authority in relation to the registration of medicines; to provide for the Zimbabwe Regional Medicines Control Laboratory and for its functions; to provide for the appointment of a Director-General of the Authority and for the keeping of a Medicines Register; to provide for certain prohibitions, controls and restrictions relating to medicines and other substances; and to provide for matters connected with or incidental to the foregoing.

[Date of commencement: 1st September, 1969.]

PART I
PRELIMINARY

1 Short title

This Act may be cited as the Medicines and Allied Substances Control Act [*Chapter 15:03*].

2 Interpretation

(1) In this Act—

"advertisement", in relation to any medicine, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

(a) appearing in any newspaper or other publication; or

(b) appearing on any television or cinematograph film; or

(c) distributed to members of the public; or

(d) brought to the notice of members of the public in any manner whatsoever;

which is intended to promote the sale of that medicine;

"analyst" means a person who is an analyst, pathologist or person having a special knowledge of the action and application of medicines appointed in terms of paragraph (*b*) of subsection (1) of section *sixty-five* for the purpose of the testing, examination or analysis of medicines in terms of this Act;

"approved name", in relation to a medicine , means the internationally recognized non-proprietary name of that medicine or any other name approved by the Authority;

"Authority" means the Medicines Control Authority of Zimbabwe established by section *three*;

"clinical trial" means a systematic study in human beings or animals in order to establish the efficacy of, or to discover or verify the effects or adverse reactions of medicines, and includes a study of the absorption, distribution, metabolism and excretion of medicines;

"Council"

repealed by Act 1 of 1996 with effect from 1 August, 1997]

"dental practitioner" means a person registered as such under the Health Professions Act [*Chapter 27:19*];

amended by Act 6/2000 with effect from 2 April, 2001.

"Director-General" means the Director-General of the Authority appointed in terms of section *twenty-six*;

"Director of the Laboratory" means the Director of the Laboratory appointed in terms of section *twenty-five C*;

"drug"

repealed by Act 1 of 1996 with effect from 1 August,1997 – see note in Part V - Editor

"former Council" means the Drugs Control Council which was in existence in terms of this Act immediately before the 1st August, 1997;

"inspector" means a person appointed in terms of paragraph (*a*) of subsection (1) of section *sixty-five* to be an inspector;

"Laboratory" means the Zimbabwe Regional Medicines Control Laboratory referred to in section *twenty-five A*;

"manufacture" includes compound, process or pack for sale but does not include the compounding of a medicine by a medical practitioner, dental practitioner, veterinary surgeon or pharmacist if that medicine—

(a) has not been advertised for sale in Zimbabwe; and

(b) does not contain any component the sale of which is prohibited by this Act; and

(c) is supplied for the treatment of a particular person or animal;

amended by R.G.N. 899 of 1978 with effect from 17 November,1978.

"medical practitioner" means a person registered as such under the Health Professions Act [*Chapter 27:19*];

amended by Act 6/2000 with effect from 2 April, 2001.

"medicine", subject to section *seventy-five*, means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in—

(a) the diagnosis, treatment, mitigation or prevention of disease or any abnormal physical or mental state or the symptoms thereof in man or in animals; or

(b) restoring, correcting or modifying any physical, mental or organic function in man or in animals;

"member" means a member of the Authority;

"Minister" means the Minister of Health and Child Welfare or any other Minister to whom the President may, from time to time, assign the administration of this Act;

By SI 161 of 2012 , the Minister of Health and Child Welfare was re-assigned.

"package" means anything in or by which any medicine is enclosed, covered, contained or packed;

"pharmaceutical chemist"

repealed by Act 1 of 1996 with effect from 1 August,1997]

" pharmacist " means a person registered as such under the Health Professions Act [*Chapter 27:19*];

amended by Act 1 of 1996 with effect from 1 August,1997
and by Act 6/2000 with effect from 2 April, 2001.

"possess" includes keep, store or have in custody or under control or supervision;

"Register" means the Medicines Register kept in terms of section *twenty-seven*;

"registered" means registered in terms of this Act;

"registered name", in relation to a registered medicine , means the approved name or generic name under which that medicine is registered;

"Registrar"

repealed by Act 1 of 1996 with effect from 1 August, 1997]

"Secretary" means the Secretary of the Ministry for which the Minister is responsible;

"sell" means sell by wholesale or retail and includes—

(a) import;

(b) export;

(c) advertise, label, prepare, expose, offer or possess for sale;

(d) smuggle, administer, hawk, supply, barter or dispose of to any person;

(e) distribute, deliver or transmit by way of gift or sample or in any other way whatsoever;

"specified medicine" means a medicine which is declared in terms of section *twenty-eight* to be a specified medicine for the purposes of this Act if the declaration is in operation in terms of subsection (2) of that section in relation to that medicine;

"veterinary medicine" means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in—

(a) the diagnosis, treatment, mitigation or prevention of disease or abnormal physical or mental state or the symptoms thereof in an animal; or

(b) restoring, correcting or modifying any physical, mental or organic function in an animal.

"veterinary surgeon" means a person registered as such under the Veterinary Surgeons Act [*Chapter 27:16*].

(2) Where a medicine is required by this Act to be labelled with any information, such information shall be written, printed or otherwise marked on a label which is—

(a) attached or affixed to the package of that medicine ; or

(b) packed with and refers to that medicine.

PART II

MEDICINES CONTROL AUTHORITY

3 Establishment of Medicines Control Authority of Zimbabwe

There is hereby established an authority, to be known as the Medicines Control Authority of Zimbabwe, which shall be a body corporate capable, in its corporate name, of suing and being sued and, subject to this Act, of performing all acts that bodies corporate may by law perform.

3A Succession to former Council

The Authority shall for all purposes be the successor to the former Council.

4 Constitution of Authority

(1) The Authority shall consist of not less than 8 and not more than 12 members as may from time to time be determined and appointed, subject to subsection (2), by the Minister.

(2) Of the members appointed in terms of subsection (1)—

(a) 1 shall be a **medical practitioner** engaged in general medical practice, chosen from a list of not less than 3 names submitted by the Zimbabwe Medical Association; and

(b) 1 shall be a **veterinary surgeon**, chosen from a list of not less than 3 names submitted by the Council of Veterinary Surgeons of Zimbabwe; and

(c) 1 shall be a **pharmacist** who is not an officer of the Ministry for which the Minister is responsible, chosen from a list of not less than 3 names submitted by the Pharmaceutical Society of Zimbabwe; and

(d) 1 shall be a **medical officer** of health for a local authority, chosen from a list of not less than three names submitted by the Urban Councils Association: and

(e) 1 shall be a registered **legal practitioner** of not less than 5 years' standing, chosen from a list of not less than 3 names submitted by the Law Society of Zimbabwe; and

(f) 1 shall be a medical practitioner who is a **specialist physician**; and

(g) 1 shall have a special knowledge of the action and application of medicines; and

(h) 1 shall be an officer of the Ministry for which the Minister is responsible who is either a pharmacist or a medical officer.

(3) The Minister shall designate one member as chairman of the Authority and another member as vice-chairman of the Authority and the vice-chairman shall exercise the functions and powers and perform the duties of the chairman during any period that the chairman is unable to exercise his functions:

Provided that the Minister shall not designate a member who is in the full-time employment of the State as chairman or vice-chairman, as the case may be, of the Authority.

(4) If any organization referred to in subsection (2) fails or refuses to submit a list of nominees for appointment to the Authority when required to do so by the Minister, the Minister may appoint any person to represent that organization, and the person so appointed shall hold office as a member in all respects as if he had been duly nominated and appointed in terms of subsection (2).

(5) If any organization referred to in subsection (2) ceases to exist, the Minister shall obtain a list of names for the purposes of that subsection from such other organization as the Minister recognizes as the successor to the first-mentioned organization.

5 Conditions of office of members

(1) Subject to this Part, a member shall hold office for such period, **not exceeding 5 years**, as the Minister may fix on his appointment.

(1*a*) On the expiry of the period for which a member was appointed, he shall continue to hold office until he has been reappointed or his successor has been appointed:

Provided that a member shall not continue to hold office in terms of this subsection for longer than 6 months.

(2) Subject to section *twelve*, a member shall hold office on such conditions as the Minister may in his case fix.

(3) A retiring member shall be eligible for reappointment as a member.

6 Disqualification for appointment as member

(1) The Minister shall not appoint a person as a member and no person shall be qualified to hold office as a member who—

(a) is not a citizen of Zimbabwe permanently resident in Zimbabwe; or

(a1) has, or is married to a person who has, a financial interest in any business, or is, or is married to a person who is, engaged in any activity connected with any business, if, in the opinion of the Minister, such financial interest or activity is likely to interfere with the impartial discharge by that person of his duties as a member; or

(b) has, in terms of a law in force in any country—

(i) been adjudged or otherwise declared insolvent or bankrupt and has not been rehabilitated or discharged; or

(ii) made an assignment to or arrangement or composition with his creditors which has not been rescinded or set aside; or

(c) has, within the period of 5 years immediately preceding the date of his proposed appointment, been convicted—

(i) within Zimbabwe of a criminal offence; or

(ii) outside Zimbabwe of an offence, by whatever name called, which, if committed within Zimbabwe, would have been a criminal offence;

and sentenced to a term of imprisonment imposed without the option of a fine, whether or not any portion has been suspended, and has not received a free pardon; or

(d) has been registered in a register kept in terms of the Health Professions Act [*Chapter 27:19*] or the Veterinary Surgeons Act [*Chapter 27:15*] and is disqualified or suspended in terms of that Act from carrying on the profession or calling in respect of which he was so registered, while he is so disqualified or suspended;

amended by Act 6/2000 with effect from 2 April, 2001.

or

(e) has, subject to subsection (2), a direct or indirect interest in the sale of any medicine .

(2) For the purposes of paragraph (*e*) of subsection (1), a medical practitioner, dental practitioner, veterinary surgeon or pharmacist shall not be deemed to have an interest in the sale of any medicine by reason only of the fact that—

(a) in the case of a medical practitioner, dental practitioner or veterinary surgeon, he sells the medicine in the course of his professional activities;

amended by R.G.N. 899 of 1978 with effect from 17 November,1978.

(b) in the case of a **pharmacist**, he sells the medicine in the course of any business carried on by him in terms of the Shop Licences Act [*Chapter 14:17*].

7 Vacation of office of member

A member shall vacate his office and his office shall become vacant—

(a) 1 month after the date he gives notice in writing to the Minister of his intention to resign his office or after the expiration of such shorter period as he and the Minister may agree; or

(b) 30 days after the date he is sentenced by a court to imprisonment referred to in paragraph (c) of subsection (1) of section *six* after conviction of an offence referred to in that paragraph:

Provided that if, during the said period of 30 days, an application for a free pardon is made or an appeal is filed the question whether the member is to vacate his office shall not be determined until the final disposal of such application or appeal, whereupon the member shall forthwith vacate his office and his office shall become vacant unless he is granted a free pardon, his conviction is set aside or a punishment other than imprisonment is substituted; or

(c) if he becomes disqualified in terms of paragraph (*a*), (*b*), (*d*) or (*e*) of subsection (1) of section *six* to hold office as a member; or

(d) if he is required in terms of section *eight* to vacate his office; or

(e)

repealed by Act 1 of 1996 with effect from 1 August,1997]

(f) if he ceases to hold a qualification which was necessary in terms of subsection (2) of section *four* for his appointment.

8 Minister may require member to vacate office or suspend him

(1) The Minister may require a member to vacate his office if the Minister is satisfied that the member—

(a) has been guilty of improper conduct as a member; or

(b) has failed to comply with the conditions of his office fixed by the Minister in terms of subsection (2) of section *five*; or

(c) is mentally or physically incapable of efficiently performing his duties as a member.

(2) The Minister may suspend from office a member against whom criminal proceedings are instituted for an offence in respect of which a sentence of imprisonment without the option of a fine may be imposed, and whilst that member is so suspended he shall not carry out any duties as a member.

(3) The Minister, on the recommendation of the Authority, may require a member to vacate his office if the Minister is satisfied that the member has been absent, without the permission of the Authority, from 2 consecutive meetings of the Authority of which he was given at least 7 days' notice, and that there was no just cause for the member's absence.

9 Filling of vacancies on Authority

On the death of, or vacation of office by, a member, the Minister may, subject to this Part, appoint a person to fill the vacancy:

Provided that, if as a result of the vacancy the number of members is fewer than the minimum specified in subsection (1) of section *four*, the Minister shall appoint a person to fill the vacancy.

10 Meetings and procedure of Authority

(1) The Authority shall hold its first meeting on such date and at such place as the Minister may fix and thereafter the Authority shall meet for the dispatch of business and adjourn, close and otherwise regulate its meetings and procedures as it thinks fit:

Provided that a meeting of the Authority shall be held not less than **once in every 3 months**.

(2) The chairman of the Authority—

(a) may himself, at any time, convene a meeting of the Authority;

(b) shall, at the request in writing of not less than 4 members, convene a special meeting of the Authority which meeting shall be convened for a date not less than 7 days or more than 30 days after receipt of such request.

(3) The chairman or, in his absence, the vice-chairman shall preside at all meetings of the Authority:

Provided that, if the chairman and the vice-chairman are both absent from a meeting of the Authority, the members present may elect one of their number to preside at that meeting as chairman.

(3*a*) The vice-chairman of the Authority shall perform the chairman's functions during any period that the chairman is for any reason unable to perform them.

(4) A majority of members shall form a quorum at a meeting of the Authority.

(5) All acts, matters or things authorized or required to be done by the Authority shall be decided by a majority vote at a meeting of the Authority at which a quorum is present.

(6) At all meetings of the Authority each member present shall have 1 vote on a question before the Authority and, in the event of an equality of votes, the chairman shall have, in addition to a deliberative vote, a casting vote.

11 Committees of Authority

(1) For the better exercise of its functions and powers the Authority—

(a) shall establish an executive committee, the function of which shall be to exercise any powers of the Authority between meetings:

Provided that—

(i) the executive committee shall not, save in so far as the Authority otherwise directs, have power to set aside or vary any decision of the Authority;

(ii) any action taken by the executive committee shall be reviewed by the Authority at its meeting next after such action is taken;

(a1) shall establish a committee to be known as the Laboratory committee, in which may be vested and on which may be imposed such of the functions and powers of the Authority in relation to the Laboratory as the Authority may direct:

Provided that—

(i) the vesting or imposition of any such function or power in the Laboratory committee shall not thereby divest the Authority of that function or power:

(ii) the Authority may amend or withdraw any decision of the Laboratory committee in the exercise of its functions and powers;

(b) may establish any other committees in which may be vested and on which may be imposed such of the functions and powers of the Authority as the Authority may direct:

Provided that—

(i) the vesting or imposition of any such functions and powers in a committee shall not thereby divest the Authority of such functions and powers;

(ii) the Authority may amend or withdraw any decision of any such committee in the exercise of its functions and powers.

(2) The chairman of the Authority or of a committee may, at any time and at any place, convene a meeting of that committee.

(3) The procedure of a committee shall be fixed by the Authority.

(4) On the establishment of—

(a) the executive committee, the Authority shall appoint to that committee such members of the Authority as it thinks fit;

(a1) the Laboratory committee, the Authority shall appoint to that committee—

(i) at least 1 member of the Authority, who shall be the chairman of that committee; and

(ii) a representative from the Ministry for which the Minister is responsible, who shall have special knowledge of the action and application of medicines; and

(iii) a representative from the Zimbabwe National Family Planning Council established by section 3 of the Zimbabwe National Family Planning Council Act [15:11]; and

(iv) a chemical analyst; and

(v) not more than 3 other persons who are not members of the Authority;

(b) a committee other than the executive committee or the Laboratory committee, the Authority—

(i) shall appoint thereto at least 1 member of the Authority who shall be the chairman of that committee;

(ii) may appoint thereto persons who are not members of the Authority.

12 Remuneration and expenses of members of Authority or committee

A member of the Authority or of a committee of the Authority shall be paid from the funds of the Authority such allowances as the Minister, after consultation with the Authority, may fix.

12A Disclosure of interest by members of Authority and committees

(1) If a member of the Authority or of a committee of the Authority or a spouse of such member—

(a) tenders for or acquires or holds a direct or indirect pecuniary interest in a contract with the Authority or in any application for the registration of a medicine under consideration by the Authority; or

(b) knowingly acquires or holds a direct or indirect pecuniary interest in a company or association of persons applying for the registration of a medicine by the Authority; or

(c) owns immovable property or holds a right in immovable property or a direct or indirect pecuniary interest in a company or association of persons which results in his private interest coming or appearing to come into conflict with his duties as a member;

the member shall forthwith disclose the fact to the Authority or to the committee, as the case may be.

(2) A member referred to in subsection (1) shall take no part in the consideration or discussion of, or vote on, any question before the Authority or the committee, as the case may be, which relates to any contract, right, immovable property, interest or registration of a medicine referred to in that subsection.

13 Funds, accounts and audit

(1) The funds of the Authority shall consist of—

(a) such fees as are payable in terms of regulations made under section *seventy-four*; and

(b) such moneys as may be payable to the Authority from moneys appropriated for the purpose by Act of Parliament; and

(c) such other moneys and assets as may vest in or accrue to the Authority, whether in the course of its functions or otherwise:

Provided that the Authority shall not accept any donation or bequest without the approval of the Minister after consultation with the Minister responsible for finance.

(2) The Authority shall keep proper accounts and other records relating thereto in respect of its funds.

(3)

repealed by Act 1 of 1996 with effect from 1 August,1997

(4) The accounts of the Authority shall be examined and audited by the Auditor-General or a person who is registered as a public auditor in terms of the Public Accountants and Auditors Act [*Chapter 27:12*].

[amended by GLA2015 w.e.f. June,2015]

13A Annual report of Authority

(1) The Authority shall, as soon as possible and in any case **not later than 6 months** after the end of the financial year concerned, submit to the Minister a report in regard to the affairs of the Authority during each financial year.

(2) A report submitted in terms of subsection (1) shall include a copy of the Authority's balance sheet and income and expenditure account.

(3) The Minister shall lay a report submitted to him by the Authority in terms of subsection (1) before Parliament.

14 Powers of Authority

For the better exercise of its functions the Authority shall, subject to this Act, have power to do or cause to be done all or any of the things specified in the *First Schedule*.

14A Pensions benefits for certain employees of Authority

With the approval of the Public Service Commission and the Minister responsible for finance, the Authority may require any of its employees who have been transferred from the Public Service to the service of the Authority to continue paying contributions to the Consolidated Revenue Fund for pensions purposes, and thereupon—

(a) the *Second Schedule* shall apply in respect of the employee; and

(b) subject to the *Second Schedule*, the employee shall pay contributions to the Consolidated Revenue Fund as if he were a member of the Public Service.

15 Validity of decisions and acts of Authority

No decision or act of the Authority or act done under the authority of the Authority shall be invalid by reason only of the fact that—

(a) the Authority consisted of less than the minimum number of persons for which provision is made in subsection (1) of section *four*; or

(b) the various members did not satisfy the requirements of subsection (2) of section *four*; or

(c) a disqualified person acted as a member at the time a decision was taken or the act was done or authorized;

if the decision was taken or the act was done or authorized by a majority vote of the persons who at the time were entitled to act as members.

PART III
CLINICAL TRIALS

16 Conduct of clinical trials

(1) No person shall conduct a clinical trial of any medicine without the prior written authorization of the Authority, granted with the approval of the Secretary.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

17 Application for conduct of clinical trials

(1) Any person wishing to conduct a clinical trial of a medicine shall submit to the Director-General an application in the prescribed form, signed by him and accompanied by such fee as may be prescribed.

(2) In the case of a medicine for the treatment of persons, the application referred to in subsection (1) shall set out the names of all persons who will take part in the clinical trial, together with such other relevant particulars relating to the physical identification of such persons as may be prescribed.

(3) In the case of a medicine for the treatment of animals, the application referred to in subsection (1) shall specify the kinds of animals that will take part in the clinical trial, and the names and addresses of the owners thereof.

(4) Where a clinical trial is to be conducted in a hospital or other medical institution, the application referred to in subsection (1) shall be countersigned by the medical superintendent or a senior medical officer of comparable rank of such hospital or medical institution.

18 Director-General to submit applications to Authority

(1) Upon receipt of an application in terms of subsection (1) of section *seventeen*, the Director-General shall submit it to the Authority for consideration, together with his comments thereon, as soon as possible.

(2) If, after due consideration, the Authority is satisfied that the application should be granted, it shall consult with, and obtain from, the Secretary written approval for the clinical trial, and thereafter issue written authorization in the prescribed form to the applicant to conduct the trial.

(3) Any person who is aggrieved by a decision of the Secretary not to grant written approval for the conduct of a clinical trial may appeal to the Minister, whose decision shall be final.

19 Conditions for conduct of clinical trials

(1) Any clinical trial of any medicine authorized in terms of section *eighteen* shall be subject to such specific and general conditions as the Authority may, with the approval of the Secretary, impose and, for the safety of all persons or animals taking part in such trial, the person conducting the trial shall observe strictly all the conditions subject to which the trial is authorized.

(2) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

20 Consents for clinical trials

(1) Where the Authority grants written authorization under section *eighteen* for the conduct of a clinical trial of a medicine, no such trial shall take place until—

(a) in the case of a medicine for the treatment of **adult** persons, the voluntary written consents of all such persons taking part in the clinical trial have been freely obtained; and

(b) in the case of a medicine for the treatment of **minors** or persons under legal disability, the voluntary written consents of their parents or legal guardians, as the case may be, have been freely obtained; and

(c) in the case of a medicine for the treatment of **animals**, the voluntary written consents of the owners of all animals taking part in the clinical trial have been freely obtained;

by the person conducting the trial.

(2) Any person who commences a trial before the consents required by subsection (1) have been obtained shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

21 Supply of information prior to clinical trials *etc.*

(1) Whenever a clinical trial of any medicine is authorized in terms of section *eighteen*, the person conducting the trial shall, before commencing the trial—

(a) inform all persons taking part in the trial or persons whose animals will take part in the trial about—

(i) the aims and objectives of the clinical trial and the way in which it will be conducted; and

(ii) the possible risks, discomforts and other adverse effects that may result therefrom;

and

(b) insure in such amount as may be prescribed from time to time all persons or animals taking part in the trial against any injury or risk of injury that may be sustained during the trial; and

(c) sign an indemnity in such form as may be prescribed, indemnifying the State, the Secretary and the Authority from liability in respect of any injury or adverse effect whatsoever which may be sustained by any person or animal, directly or indirectly, as a result of the conduct of the trial and which occurs or reveals itself at the time of the trial or subsequently.

(2) Any person who commences a trial without complying with the requirements of subsection (1) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

22 Council's power to stop or suspend clinical trials

If at any stage during the clinical trial of any medicine authorized in terms of section *eighteen*, the Authority is satisfied that having due regard to the initial risks, discomforts or other adverse effects caused to persons or animals taking part in the trial it is in the public interest to stop or suspend the trial, it shall seek and obtain forthwith the Secretary's written approval to stop or suspend the trial immediately, and, if such approval is obtained, the Authority shall notify in writing the person conducting the trial accordingly.

23 Monitoring of clinical trials by Authority

To ensure adequate protection of the general public against any risks or adverse effects from the clinical trial of any medicine authorized in terms of section *eighteen*, the Authority shall monitor such clinical trial from the beginning to the end so as to satisfy itself that all specific and general conditions subject to which the trial was authorized are being strictly observed by the person conducting the trial, and that to all intents and purposes the trial will achieve its aims and objectives.

24 Reports on clinical trials

(1) **Not later than 30 days** after the completion of a clinical trial authorized in terms of section *eighteen*, the person who conducted the trial shall compile and submit to the Secretary through the Authority a preliminary report on the ethical evaluation of the trial.

(2) In addition to the report referred to in subsection (1), the person who conducted the trial shall, **not later than 90 days** after the completion of the trial, compile and submit to the Secretary through the Authority a comprehensive report on any serious or adverse effects or reaction established by the trial.

(3) Pursuant to the duty imposed upon it in terms of section *twenty-three*, the Authority shall, **not later than 90 days** after the satisfactory completion of a clinical trial, compile and submit to the Secretary an independent comprehensive report giving its factual assessments and findings on the trial as a whole, together with any recommendations that it may wish to make.

(4) Any person who contravenes subsection (1) or (2) shall be guilty of an offence and liable to a fine not exceeding level seven or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

25

repealed by Act 22 of 2001 with effect from 20th May, 2002

PART IIIA

ZIMBABWE REGIONAL MEDICINES CONTROL LABORATORY

25A Transfer of Laboratory to Authority

With effect from the 1st August, 1997—

(a) the Zimbabwe Regional Drug Control Laboratory which was operated by the State shall be transferred to and vest in the Authority;

(b) the Laboratory referred to in paragraph (*a*) shall be known as the Zimbabwe Regional Medicines Control Laboratory.

25B Functions of Laboratory

The Laboratory shall be responsible for—

(a) verifying the quality, safety and efficacy of any medicines and allied substances referred to it by any person in Zimbabwe or elsewhere; and

(b) verifying the standards of specifications of any medicines and allied substances referred to it by any person in Zimbabwe or elsewhere; and

(c) training persons in the analysis of medicines and allied substances; and

(d) performing any other function relating to the analysis of medicines and other substances which the Minister, with the approval of the Authority, may direct or authorize the Laboratory to perform.

25C Director of the Laboratory

(1) Subject to this Act, the Authority, in consultation with the Minister, shall appoint a person who has a special knowledge of the pharmaceutical analysis of medicines to be the Director of the Laboratory.

(2) Subject to the control of the Authority, the Director of the Laboratory shall be—

(a) responsible for managing the operations of the Laboratory;

(b) responsible for training analysts in the analysis of medicines and allied substances;

(c) secretary to the Laboratory committee, in which connection he shall, on the instructions of the chairman of that committee, convene meetings of the committee and maintain the records of such meetings.

PART IV

REGISTRATION OF MEDICINES

26 Director-General of Authority

(1) Subject to this section, for the better exercise of its functions the Authority, in consultation with the Minister, shall appoint a person who has special knowledge of the action and application of medicines to be the Director-General of the Authority.

(1*a*) The Director-General's appointment shall be on such terms and conditions as the Authority, with the approval of the Minister, may fix.

(2) Subject to paragraph (*d*) of subsection (2) of section *twenty-fiveB*, the functions of the Director-General shall be—

(a) to be the secretary to the Authority, in which connection he shall, on the instructions of the chairman of the Authority, convene meetings of the Authority and any committee thereof and maintain the records of any such meeting; and

(a1) subject to the control of the Authority—

(i) *to manage the operations and property of the Authority;*

(ii) *to supervise and control the activities of the employees of the Authority in the course of their employment;*

(b) to carry out any other duties imposed on him by or in terms of this Act.

(3) Whenever the Director-General is absent or unable to carry out any of his functions under this Act or any other enactment, a deputy Director-General shall exercise such of the Director-General's functions as the chairman of the Authority may designate.

27 Medicines Register

(1) Subject to subsection (2), the Director-General shall keep a register, to be known as the Medicines Register, in a form approved by the Minister, in which he shall enter—

(a) the particulars of any medicine which the Authority has directed him to register, including the conditions, if any, subject to which that medicine has been registered;

(b) the cancellation of the registration or variation of the conditions of registration of any medicine in terms of this Act.

(2) The Register shall be in 2 parts as follows—

(a) Part I relating to medicines which are not veterinary medicines;

(b) Part II relating to veterinary medicines.

(3) The Register which, immediately before the 1st October, 1978, was being kept in terms of this section shall, on and after that date, continue to be kept in terms of this section as Part 1 of the Register.

28 Declaration of specified medicines

(1) Subject to subsection (2), the Minister, after consultation with the Authority, may at any time, by *statutory instrument*, declare any medicine or class of medicines to be a specified medicine for the purposes of this Act.

(2) A notice in terms of subsection (1) shall specify whether any medicine declared to be a specified medicine in terms of subsection (1) is a medicine which is not a veterinary medicine or is a veterinary medicine.

(3) A declaration in terms of subsection (1) in relation to a medicine which, immediately before the date of publication of the statutory instrument—

(a) was available for sale in Zimbabwe, shall come into operation on such date as may be fixed in that statutory instrument;

(b) was not available for sale in Zimbabwe, shall come into operation on the date of publication of that statutory instrument.

(4) Any notice made in terms of subsection (1) and in force immediately before the 1st October, 1978, shall, on and after that date, be deemed to have declared medicines which are not veterinary medicines to be specified medicines for the purposes of this Act.

29 Sale of specified medicines

(1) Subject to this section, no person shall sell any specified medicine—

(a) unless it is registered; and

(b) if it is registered subject to any conditions, otherwise than in accordance with such conditions.

(1a) Subject to subsections (2) and (3), any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

(2) Where a specified medicine which was available for sale in Zimbabwe before it became a specified medicine has not been registered but notification has been published in the *Gazette* in terms of paragraph (*c*) of subsection (2) of section *thirty-one* that application for the registration of that medicine has been made, a person may thereafter sell that specified medicine until notification is published in the *Gazette*—

(a) in terms of subsection (4) of section *thirty-one*, that the application for the registration of that medicine has been withdrawn; or

(b) in terms of section *thirty-two*, that the application for the registration of that medicine has lapsed; or

(c) in terms of subsection (6) of section *thirty-three*, that the Authority has approved or refused to approve, as the case may be, the registration of that medicine.

(3) Subsection (1) shall not apply in relation to the sale of a medicine compounded by a medical practitioner, pharmacist, dental practitioner or veterinary surgeon if that medicine—

(a) has not been advertised for sale in Zimbabwe; and

(b) does not contain any component the sale of which is prohibited by this Act; and

(c) is supplied for the treatment of a particular person or animal.

amended by R.G.N. 899 of 1978 with effect from 17 November,1978.

30 Registrability of medicines

(1) The Authority shall approve the registration of a medicine if it considers that—

(a) the availability of that medicine is in the public interest; and

(b) the safety, quality and therapeutic efficacy of that medicine—

(i) *in the case of a medicine which is not a veterinary medicine, in relation to its effect on the health of man;*

(ii) *in the case of a veterinary medicine, in relation to its effect on the health of animals;*

warrant its registration; and

(c) in the case of a medicine manufactured in Zimbabwe, the premises at which it is manufactured and all processes of manufacture are satisfactory.

(2) Notwithstanding subsection (1), the Authority shall not approve the registration of any medicine manufactured outside Zimbabwe, unless a valid certificate of registration in respect of such medicine issued by the appropriate authority established for the registration of medicines in the country of origin of that medicine has been produced to the satisfaction of the Authority.

31 Applications for registration of medicines

(1) An application for the registration of a medicine shall be submitted to the Director-General in the prescribed form and accompanied by the prescribed fee payable in respect of an application for the registration of a medicine.

(2) As soon as possible after receiving an application in terms of subsection (1) the Director-General shall—

(a) submit the application, together with the particulars and samples which accompanied the application, to the Authority; and

(b) notify the applicant that the application has been so submitted; and

(c)

repealed by Act 1 of 1996 with effect from 1 August,1997]

(3) An application in terms of subsection (1) may at any time be withdrawn by the applicant but such withdrawal shall not entitle the applicant to the refund of the application fee referred to in subsection (1).

(4)

repealed by Act 1 of 1996 with effect from 1 August,1997

32 Lapsing of application for registration of medicine

If the annual fee payable for the retention of the right to sell an unregistered specified medicine referred to in subsection (2) of section *twenty-nine* is not paid within such period as may be prescribed, the application for the registration of that medicine shall lapse forthwith, and the Director-General shall cause notification thereof to be published in the *Gazette.*

33 Registration of medicines

(1) After receiving an application in terms of section *thirty-one* the Authority—

(a) shall conduct such investigation or inquiry as it considers necessary or desirable, including hearing evidence from the applicant;

(b) may require further particulars or samples from the applicant.

(2) If the Authority—

(a) approves the registration of any medicine, it shall notify the Director-General thereof and the Director-General shall thereupon—

(i) enter in the Register the prescribed particulars of the medicine and any condition fixed in terms of subsection (3); and

(ii) allocate a registered number to the medicine; and

(iii) issue to the applicant a certificate of registration in the prescribed form showing the registered number of that medicine and any conditions subject to which it is registered;

(b) refuses to approve the registration of a medicine, it shall, subject to subsection (4), notify the Director-General thereof, together with its reasons, and the Director-General shall thereupon inform the applicant in writing—

(i) of such refusal and the reasons therefor, and

(ii) that he may, if he so wishes, appeal to the Administrative Court in terms of Part VII.

(3) If, in the opinion of the Authority, a medicine should be registered only if it is distributed or advertised in a particular manner or distributed subject to certain safeguards, it shall, in approving the registration of that medicine, fix any such conditions as it considers to be necessary or desirable.

(3a) Any person who distributes or advertises a medicine in contravention of any condition fixed in terms of subsection (3) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

(4) Where the Authority intends—

(a) to refuse to approve the registration of a medicine; or

(b) to register a medicine subject to conditions fixed in terms of subsection (3);

the Authority shall notify the Director-General thereof, together with its reasons, and the Director-General shall thereupon inform the applicant in writing of such intention and the reasons therefor and that he may, if he so wishes, make, within such period being **not less than 14 days** as the Authority may specify, representations in relation to the intentions of the Authority.

(5) A medicine shall be registered under its approved name.

(6) Where the Authority approves or refuses to approve the registration of a medicine, the Director-General shall cause to be published in the *Gazette* notification of such approval or refusal to approve registration, as the case may be, and, if the medicine has been registered subject to any conditions, the conditions subject to which the medicine has been registered:

Provided that in the case of a medicine which the Authority has refused to register, the Director-General shall not publish notification of such refusal until the period specified in section *sixty-two* for the lodging of an appeal has expired or, if the person has appealed in terms of Part VII against the decision of the Authority, until such time as the appeal has been abandoned or determined in terms of that Part.

34 Cancellation and variation of conditions of registration

(1) If the Authority is of the opinion that—

(a) any person has failed to comply with the conditions subject to which a medicine has been registered; or

(b) the annual fee payable for the retention of the registration of a registered medicine referred to in paragraph (*g*) of subsection (2) of section *seventy-four* has not been paid; or

(c) a registered medicine does not comply with any prescribed requirements; or

(d) a registered medicine has been advertised in Zimbabwe in an advertisement which is false or misleading or does not comply with section *forty*; or

(e) it is not in the public interest that a registered medicine should be made or continue to be made available to the public; or

(f) it is in the public interest to vary the conditions of registration of a registered medicine;

the Authority shall direct the Director-General to give notice thereof in writing to the person by whom or on whose behalf the application for the registration of that medicine was made:

Provided that, where the annual fee payable for the retention of the registration of a registered medicine in terms of paragraph (*b*) has not been paid, the Authority need not direct the Director-General to give notice to the person concerned under this subsection but may direct the Director-General forthwith to cancel the registration concerned

(2) A notice given in terms of subsection (1) shall—

(a) specify the grounds on which the opinion of the Authority is based; and

(b) indicate that the person to whom it is directed may, within one month after the receipt thereof, submit to the Director-General any comments he may wish to put forward in connection with the matter.

(3) If—

(a) no comments are submitted in terms of paragraph (*b*) of subsection (2); or

(b) after consideration of any comments submitted in terms of paragraph (*b*) of subsection (2) the Authority is of the opinion for any reason specified in subsection (1) that the registration of the medicine should be cancelled or the conditions of registration be varied;

the Authority shall direct the Director-General to cancel or to vary the conditions of registration of that medicine.

(4) On the cancellation or variation of the conditions of registration of a medicine in terms of the proviso to subsection (1) or subsection (3) the Director-General shall cause to be published in the *Gazette* notification of that cancellation or variation of conditions:

Provided that the Director-General shall not publish notification of such cancellation or variation of conditions until the period specified in section *sixty-two* for the lodging of an appeal has expired or, if the person has appealed in terms of Part VII against the decision of the Authority, until such time as the appeal has been abandoned or determined in terms of that Part.

35 Notifications in professional journals

(1) The Director-General may cause to be published in such professional journals of the medical, dental, veterinary and pharmaceutical professions published in Zimbabwe as the Authority may approve details of—

(a) any application for the registration of a medicine;

(b) the withdrawal or lapsing of any application for the registration of a medicine;

(c) the approval of or the refusal to approve, as the case may be, the registration of any medicine, including, in the case of a registered medicine, any condition subject to which the medicine has been registered;

(d) the cancellation of the registration of any medicine.

(2) The cost of any publication in terms of subsection (1) shall be paid from the funds of the Authority.

36 Medicines to be labelled

(1) Subject to this section, no person shall sell any registered medicine unless it is labelled with its registered name and registered number, in addition to any other prescribed requirements.

{See Section 11(a) **Complementary** Medicines Regulations, 2015. SI 97/2015

(1a) Subject to subsections (2), (3) and (4), any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

(2) A registered medicine which is sold by—

(a) a medical practitioner, dental practitioner or veterinary surgeon for the treatment of a particular person or animal and supplied by that medical practitioner, dental practitioner or veterinary surgeon for that person or animal;

amended by R.G.N. 899 of 1978 with effect from 17 November,1978.

or

(b) a pharmacist for the treatment of a particular person or animal and supplied by that pharmacist in accordance with a direction given by a medical practitioner, dental practitioner or veterinary surgeon;

may be sold without being labelled with the registered number of the medicine or with the other prescribed requirements but shall be labelled with the registered name of the medicine unless the medical practitioner, dental practitioner or veterinary surgeon, as the case may be, has specifically directed that it shall not be labelled with the registered name.

(3) The Minister may, after consultation with the Authority, by regulation, provide for exemptions to subsection (1).

(4) A registered medicine which has been prepared for sale before the date on which it is registered may, notwithstanding that it is not labelled in accordance with the requirements of subsection (1), be sold during such period as may be specified by the Authority by notice in the *Gazette* in relation to that medicine.

repealed by Act 1 of 1996 with effect from 1 August,1997

38 Prohibitions, controls and restrictions in respect of medicines, veterinary medicines and certain substances, devices and articles

(1) The Minister may, after consultation with the Authority, by regulation, prohibit, control or restrict—

(a) the manufacture, compounding, dispensing, possession, sale or use of any medicine;

General Regulations, 1991 SI 150/1991
Condom Regulations, 2005 SI 183/2005
Gloves Regulations, 2005 SI 1/2006
Import & Export of Precursors & Certain Chemical Substances SI 56/2008
Import & Export of Medicines Regulations, 2008 SI 57/2008
Homeopathic Remedies (**Repeal**) Regulations, 2015 SI 96/2015
Complementary Medicines Regulations, 2015 SI 97/2015

or

(b) the manufacture, possession, sale or use of—

(i) any substance which is used, or is manufactured, sold or represented as suitable for use, for cosmetic purposes or for the dressing of wounds or the stanching or absorbing of bleeding or other discharges from the body; or

(ii) any substance, device or article which is used, or is manufactured, sold or represented as suitable for use, for any purpose which brings it into contact with the body or any part thereof if, in the opinion of the Authority, such regulations are desirable in order to prevent infection or allergy or any other harmful effect resulting from that use; or

(iii) any device or article which is used, or is manufactured, sold or represented as suitable for use, in the diagnosis or treatment of any physical or mental state in man if, in the opinion of the Authority, such regulations are desirable in the public interest.

(2) In regulations referred to in subsection (1), the Minister may prescribe the precautions to be taken by a person in possession of a medicine to ensure its safe custody and the action to be taken by such person in the event of the destruction, loss or theft thereof.

(3) Any person who contravenes any provision of regulations referred to in subsection (1) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 20th May,2002; whereas the scale of fines came into force on the 10th September, 2002. This subsection (3) applies only to the breach of some, not all, regulations, and must be construed with section 106 of S.I. 150 of 1991.
- Editor.

39 Prohibition on sale of medicines which do not comply with prescribed requirements and furnishing of information regarding medicines to Authority

(1) The Minister, after consultation with the Authority, may prescribe requirements with which any medicine or component thereof must comply, including requirements as to the composition, therapeutic suitability and effect, purity or other properties and the conditions under which any medicine shall be prepared.

(2) No person shall—

(a) sell any medicine in respect of which requirements referred to in subsection (1) have been prescribed unless that medicine complies with such requirements;

(b) prepare any medicine in respect of which conditions referred to in subsection (1) have been prescribed otherwise than in accordance with such conditions.

(2a) Any person who contravenes subsection (2) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

(3) The Authority may, by notice in writing, require any person who manufactures, sells, administers or prescribes any medicine or on whose direction any medicine is administered to furnish it, within a period stipulated in such notice or such further period as the Authority may permit, with any information which that person has in his possession or which that person is in a position to obtain regarding that medicine.

(4) Any person who fails without reasonable excuse to comply with a notice in terms of subsection (3) shall be guilty of an offence and liable to a fine not exceeding level five or to imprisonment for a period not exceeding one month or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

40 Advertisement of medicines

See also the restrictions in section 6 of the Fifth Schedule to the Broadcasting Services Act *Chapter 12:06* , which came into effect on the 4th April, 2001 – Editor.]

(1) No person shall publish, distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning a medicine.

(2) If any medicine has been registered—

(a) subject to the condition that it shall be available to the public only on the direction of a medical practitioner, dental practitioner or veterinary surgeon no person shall advertise that medicine otherwise than—

(i) *in a medical, dental or veterinary or pharmaceutical journal approved by the Authority;*

amended by R.G.N. 899 of 1978 with effect from 17 November,1978.

or

(ii) *to members of the medical, dental, veterinary or pharmaceutical profession;*

(b) subject to any condition fixed in terms of subsection (3) of section *thirty-three*, no person shall advertise that medicine—

(i) *in a manner inconsistent with such condition; or*

(ii) *so as to indicate or imply that that medicine may be used or sold in a manner inconsistent with such condition.*

(2a) Any person who contravenes subsection (1) or (2) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

(3) It shall be sufficient defence in any prosecution for an offence involving a contravention of subsection (1) if it is proved to the satisfaction of the court that the accused, not being a person selling the medicine to which the false or misleading advertisement which is the subject of the prosecution relates, did not know and could not reasonably be expected to have known that the advertisement was in any respect false or misleading unless it is proved that the accused failed on demand by the Director-General, an inspector or a police officer to furnish the name and address of the person at whose instance the advertisement was published or distributed or was brought to the notice of the public.

amended by Act 22 of 2001 with effect from 20th May, 2002

41 Prohibition of sale of undesirable medicines

(1) If the Authority is of the opinion that it is not in the public interest that a specified medicine shall be available to the public it may—

(a) by notice in writing transmitted by registered post to any person, direct that person; or

(b) by notice in the *Gazette*, direct all persons;

not to sell such medicine or supply or deliver such medicine to any person for any reason whatsoever:

Provided that a notice in terms of this subsection shall not prevent the person concerned from returning the medicine to the manufacturer thereof or, in the case of an imported medicine, to the importer concerned or from supplying or delivering such medicine to a person approved by the Authority for the purpose.

(2) The Authority, with the approval of the Minister and the Minister responsible for finance, may, if it deems fit, on the application of a person who has sustained any loss by reason of compliance with a notice issued in terms of subsection (1), grant to that person from the funds of the Authority such amount as compensation for such loss as the Authority considers to be reasonable in the circumstances.

(3) Any person who sells, supplies or delivers a medicine in contravention of a notice directed to him in terms of subsection (1) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

PART V
[Repealed by the Criminal Code with effect from the 1st July, 2006.]

PART VI
LICENSING AND CONTROL OF PHARMACEUTICAL PREMISES AND PERSONS

53 Interpretation in Part VI

In this Part—

"dispense", in relation to a medicine, means to—

(a) prepare; or

(b) count out, measure or decant from a bulk supply; or

(c) mix; or

(d) dissolve; or

(e) disperse;

and dispose of the medicine, for gain or otherwise, for the treatment of a particular person or animal but does not include the actual administration of the medicine.

54 Register of licensed premises and persons

The Director-General shall keep and maintain in a form approved by the Authority a register of all premises which have been licensed and all persons who have been licensed in terms of this Part in which he shall record such particulars as may be directed by the Authority, the conditions, if any, imposed upon such licences and the cancellation, suspension or renewal of such licences.

55 Premises and persons to be licensed

(1) No person shall practise as or carry on the business of a pharmacist on any premises unless—

(a) the premises are licensed in terms of this Part for such practice or business; and

(b) the premises are under the continuous personal supervision of a person who is licensed in terms of this Part for those premises.

(2) No person shall manufacture any medicine on any premises unless—

(a) the premises are licensed in terms of this Part in respect of that business; and

(b) the premises are under the continuous personal supervision of a person who is licensed in terms of this Part for those premises.

(3) No person shall dispense any medicine to any person or animal on any premises unless—

(a) the premises are licensed in terms of this Part in respect of such dispensing; and

(b) he is the holder of a licence to dispense such medicine to persons or animals, as the case may be, on those premises.

(4) Subsections (1), (2) and (3) shall prevail over any other provision to the contrary contained in any other enactment. and nothing in any other enactment shall be deemed to authorize any person to act in contravention of subsection (1), (2) or (3).

(5) Any person who contravenes subsection (1), (2) or (3) shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

amended by Act 22 of 2001 with effect from 10 September, 2002

56 Application for licence

(1) An application for the licensing of any premises or person in terms of this Part shall be made to the Director-General in the prescribed form and shall be accompanied by the prescribed fee.

(2) As soon as possible after receiving an application in terms of subsection (1) the Director-General shall submit the application to the Authority and shall notify the applicant accordingly.

57 Licensing of premises

(1) On receipt of an application in terms of section *fifty-six* for the licensing of any premises, the Authority—

(a) shall conduct such investigation or inquiry as it considers necessary or desirable, including hearing evidence from the applicant; and

(b) may require further particulars from the applicant.

(2) In considering an application for the licensing of any premises the Authority shall have regard to—

(a) whether or not the licence is reasonably required in the interests of the public generally or any section thereof; and

(b) the suitability of the premises for the purposes for which the licence is required; and

(c) the safe custody of the medicines to be stored on the premises.

(3) Any licence granted in respect of any premises shall be of such description as in the opinion of the Authority is appropriate to the particular business or activity which the applicant proposes to carry on.

(4) If the Authority—

(a) approves the licensing of the premises, it shall notify the Director-General thereof and the Director-General shall thereupon—

(i) *enter in the register referred to in section fifty-four the prescribed particulars and any conditions fixed by the Authority in terms of subsection (5); and*

(ii) *allocate a licence number for the premises; and*

(iii) *issue to the applicant in the prescribed form a licence showing the licence number, the purposes for which the premises are licensed and any conditions fixed by the Authority in terms of subsection (5);*

(b) refuses to approve the licensing of the premises, it shall, subject to subsection (6), notify the Director-General thereof together with its reasons and the Director-General shall thereupon inform the applicant in writing—

(i) *of such refusal and the reasons therefor; and*

(ii) *that he may, if he so wishes, appeal to the Administrative Court in terms of Part VII.*

(5) Subject to subsection (6) the Authority may, in approving the licensing of any premises, fix such conditions as it may consider necessary or desirable having regard to the purposes for which the premises are to be licensed and the need for the safe custody of medicines to be stored on the premises.

(6) Where the Authority intends—

(a) to refuse to approve the licensing of premises; or

(b) to license premises subject to conditions fixed in terms of subsection (5);

the Authority shall notify the Director-General thereof, together with its reasons, and the Director-General shall thereupon inform the applicant in writing of such intention and the reasons therefor and that he may, if he so wishes, make within such period, being **not less than 14 days,** as the Authority may specify, representations in writing in relation to the intention of the Authority.

58 Licensing of persons

(1) On receipt of an application in terms of section *fifty-six* for the licensing of any person the Authority—

(a) shall conduct such investigation or inquiry as it considers necessary or desirable, including hearing evidence; and

(b) may require further particulars from the applicant.

(2) In considering an application for the licensing of any person the Authority shall have regard to—

(a) whether or not the applicant is suitably qualified for the purposes for which the licence is required; and

(b) whether or not the applicant is a fit and proper person to have a licence.

(3) If the Authority—

(a) approves the licensing of any applicant, it shall notify the Director-General who shall thereupon—

(i) *enter in the register referred to in section fifty-four the premises in respect of which the person has been licensed and any conditions fixed by the Authority in terms of subsection (4);*

(ii) *issue to the applicant a licence in the prescribed form specifying the name of the licensed person and the premises concerned;*

(b) refuses to approve the licensing of any applicant it shall, subject to subsection (5), notify the Director-General thereof together with its reasons and the Director-General shall thereupon inform the applicant in writing—

(i) *of such refusal and the reasons therefor; and*

(ii) *that he may if he so wishes appeal to the Administrative Court in terms of Part VII.*

(4) Subject to subsection (5), the Authority may in the licensing of any person fix such conditions as it may consider necessary or desirable having regard to the business or activity or premises in respect of which the person is to be licensed and the need for the safe custody of medicines to be stored or manufactured on the premises and the protection of the public in the sale, supply or dispensing of medicines.

(5) Where the Authority intends—

(a) to refuse to approve the licensing of any person; or

(b) to license a person subject to conditions fixed in terms of subsection (5);

the Authority shall notify the Director-General thereof, together with its reasons, and the Director-General shall thereupon inform the applicant in writing of such intention and the reasons therefor and that he may, if he so wishes, make within such period, being **not less than 14 days** as the Authority may specify, representations in writing in relation to the intention of the Authority.

59 General disqualifications for licences

(1) No licence in terms of this Part shall be issued or renewed in respect of any company—

(a) unless the directors or a majority thereof are citizens of or ordinarily resident in Zimbabwe:

Provided that where he considers the special circumstances of a particular case justify it, the Minister may exempt a company from this paragraph for such period as he may specify;

or

(b) while the company or a director thereof is disqualified under subparagraph (i) of subsection (3) of section *sixty-one* from being issued with a licence.

(2) No licence in terms of this Part shall be issued or renewed in respect of—

(a) any person other than a company who is not a citizen of or ordinarily resident in Zimbabwe:

Provided that where he considers the special circumstances of a particular case justify it, the Minister may exempt a person from this paragraph for such period as he may specify;

(b) any person while he is disqualified under subparagraph (i) of subsection (3) of section *sixty-one* from being issued with a licence.

(3) The issue or renewal of a licence to or in respect of a person who—

(a) is disqualified in terms of this section from holding it, shall be void;

(b) becomes disqualified in terms of this section from holding it, shall become void on the date on which the person becomes so disqualified:

Provided that, in the case of a company which has become disqualified by virtue of paragraph (a) or (b) of subsection (1) because of a change among its directors or in the particulars of any of its directors, the licence shall not become void if the disqualification is removed within 1 month of the change.

60 Validity and renewal of licences

(1) A licence issued in terms of this Part shall, unless cancelled or suspended, be valid for such period as may be prescribed and may be renewed before its expiry.

(2) An application for the renewal of a licence shall be made in such form and manner and within such period as may be prescribed and shall be accompanied by such fee as may be prescribed.

(3) On receipt of an application for the renewal of a licence, if the Authority is of the opinion that—

(a) the conditions subject to which the licence was issued have not been observed; or

(b) it would not be in the interest of the public generally or any section thereof for the licence to be renewed;

the Authority shall direct the Director-General to give notice thereof in writing to the applicant concerned.

(4) A notice given in terms of subsection (3) shall—

(a) specify the grounds on which the opinion of the Authority is based; and

(b) indicate that the applicant may, within one month after the receipt thereof, submit to the Director-General any comments he may wish to put forward in connection with the matter.

(5) If—

(a) no comments are submitted in terms of paragraph (*b*) of subsection (4); or

(b) after consideration of any comments submitted in terms of paragraph (*b*) of subsection (4), the Authority is of the opinion for any reason specified in subsection (3) that the licence concerned should not be renewed;

the Authority may direct the Director-General not to renew the licence.

(6) The Director-General shall, on receiving a direction in terms of subsection (5), make the appropriate entries in the register kept in terms of section *fifty-four*.

(7) Where a licence has not been renewed in terms of this section the Authority may, at the request of the applicant concerned, grant him, subject to the payment of such fee as may be prescribed, a temporary renewal of the licence, for such period and subject to such conditions as the Authority may specify, to enable the applicant to lodge an appeal in terms of Part VII against the decision of the Authority and such temporary renewal shall be valid until the appeal is determined or abandoned, as the case may be.

61 Cancellation, suspension, alteration and variation of licences

(1) If the Authority is of the opinion that—

(a) the conditions subject to which a licence was issued have not been observed; or

(a1) the person to whom a licence has been issued is wrongfully dealing in or supplying or possessing medicines, or has been convicted of an offence involving dishonesty; or

(b) it would be in the interests of the public generally or a section thereof for a licence to be cancelled or suspended or the purposes for which the licence was issued to be altered or for the conditions subject to which the licence was issued to be varied;

the Authority shall direct the Director-General to give notice thereof in writing to the person by whom or on whose behalf the application for the issue of a licence was made.

(2) A notice given in terms of subsection (1) shall—

(a) specify the grounds on which the opinion of the Authority is based; and

(b) indicate that the person to whom it is directed may within one month after the receipt thereof submit to the Director-General any comments he may wish to put forward in connection with the matter.

(3) If—

(a) no comments are submitted in terms of paragraph (*b*) of subsection (2); or

(b) after consideration of any comments submitted in terms of paragraph (*b*) of subsection (2), the Authority is of the opinion for any reason specified in subsection (1) that the licence concerned should be cancelled or suspended or the purposes for which the licence was issued should be altered or the conditions subject to which the licence was issued should be varied;

the Authority may direct the Director-General—

(i) *to cancel the licence and impose a period of disqualification not exceeding three years during which the person concerned shall not be issued with a licence; or*

(ii) *to suspend the licence; or*

(iii) *to alter the purposes for which the licence was issued; or*

(iv) *to vary the conditions subject to which the licence was issued;*

as the case may be.

(4) A direction given in terms of subsection (3) shall have immediate effect notwithstanding the noting of any appeal against the decision of the Authority:

Provided that where a licence has been cancelled or suspended the Authority may, subject to such conditions as it may specify, authorize the person concerned to continue to operate under the original licence until the appeal is determined or has been abandoned, as the case may be.

PART VII
APPEALS

62 Appeals

Any person who is aggrieved by a decision of the Authority in terms of this Act may, **within 30 days** after the date of that decision, appeal by notice in writing to the Administrative Court.

PART VIII
GENERAL

63 Compounding or dispensing of medicines and veterinary medicines

(1) Subject to this section, any person who compounds or dispenses a medicine or veterinary medicine shall do so according to—

(a) the pharmacopoeia prescribed in terms of subsection (2); or

(b) the directions in writing of a medical practitioner, dental practitioner or veterinary surgeon on whose prescription the medicine is prepared.

(2) The Minister, after consultation with the Authority, shall from time to time prescribe, by statutory instrument, the pharmacopoeia and any addendum or supplement thereto which shall be used for the purposes of subsection (1).

(3) Any person who contravenes subsection (1) shall be guilty of an offence and liable to a fine not exceeding level ten or to imprisonment for a period not exceeding one year or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

64 Exemption of Authority from liability

No liability shall attach to the Authority or any committee thereof or to a member of the Authority or any committee thereof for any loss or damage sustained by any person as a result of the *bona fide* exercise or performance by the Authority or any committee thereof of any power or duty conferred or imposed upon the Authority by this Act:

Provided that the provisions of this section shall not be construed so as to prevent any person from recovering by action in any competent court compensation for any loss or damage sustained by him which was caused by negligence.

65 Appointment of inspectors and analysts for purposes of this Act

(1) The Authority, in consultation with the Minister, may appoint—

(a) such persons to be inspectors as it may consider necessary for the proper enforcement of this Act; and

(b) such analysts as it may consider necessary for the purposes of the testing, examination or analysis of medicines in terms of this Act.

See Appointments gazetted on the **24th June, 2011** by GN 252/11

(2) Every person appointed as an inspector in terms of subsection (1) shall be furnished with a certificate of appointment signed by the Director-General.

(3) An inspector shall, on demand by any person affected by the exercise or performance by him of any power or function under this Act, exhibit the certificate issued in terms of subsection (2).

66 Powers of inspectors

(1) Subject to subsection (2), an inspector, customs officer or police officer above the rank of sergeant may at all reasonable times—

(a) enter upon and search any premises, place, vehicle, vessel or aircraft at or in which there is or is on reasonable grounds suspected to be any medicine or any substance, device or articles to which any regulations referred to in paragraph (*b*) of subsection (1) of section *thirty-eight* apply;

(b) inspect any medicine or any substance, device or article to which any regulations referred to in paragraph (*b*) of subsection (1) of section *thirty-eight* apply or any book, record or document found in or upon such premises, place, vehicle, vessel or aircraft;

(c) seize any such medicine, substance, device or article or any books, records or documents found in or upon such premises, place, vehicle, vessel or aircraft and appearing to afford evidence of a contravention of any provision of this Act;

(d) take so many samples of any such medicine, substance, device or article as he may consider necessary for the purpose of testing, examination or analysis in terms of this Act;

(e) enter any premises in respect of which an application for a licence has been made in terms of Part VI or which has been licensed in terms of that Part or which the inspector has reasonable grounds for believing are being used for the manufacture of a medicine or the carrying on of the business of a pharmacist in contravention of Part VI.

(2) An inspector, customs officer or police officer above the rank of sergeant may not enter upon or search any dwelling-house unless he believes on reasonable grounds that evidence relating to a contravention of this Act is to be found in that dwelling-house.

(3) A sample taken in terms of paragraph (*d*) of subsection (1) shall be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such medicine, substance, device or article or, if there is no such person or if he is absent for any reason, in the presence of any other witness and shall, in the presence of that person or witness, be dealt with as follows—

(a) the sample shall be **divided into 3 parts**, each of which shall forthwith be fastened and sealed and suitably labelled or marked in such manner as its nature may permit;

(b) **one part** shall then be transmitted to an analyst, together with a certificate in the prescribed form signed by the inspector, customs officer or police officer above the rank of sergeant;

(c) the **second part**, together with a copy of the said certificate, shall be handed or transmitted by registered post to the owner or seller of the medicine, substance, device or article or his agent;

(d) the **third part** shall be retained by the inspector, customs officer or police officer above the rank of sergeant.

(4) The analyst to whom one part of the sample has been transmitted in terms of subsection (3) shall, with all convenient speed, test, examine or analyse the sample delivered to him, and the result of the test, examination or analysis shall be stated in a certificate in the prescribed form.

(5) The owner of a medicine, substance, device or article from which a sample has been taken in terms of this section shall be entitled to be paid by the State an amount equal to the cost to him of the sample and any claim therefor shall be made in writing to the Secretary and shall be supported by such evidence as the Secretary may require.

67 Offences and penalties

(1) Any person who resists, hinders or obstructs an inspector, customs officer or police officer in the exercise of his functions under this Act shall be guilty of an offence and liable to a fine not exceeding level five or to imprisonment for a period not exceeding six months or to both such fine and such imprisonment.

(2) Any person who is over the age of 18 years and who—

(a) incites or in any way influences a person under the age of 18 years to use any medicine in contravention of this Act; or

(b) in contravention of this Act, sells any medicine to or procures any medicine for a person under the age of 18 years or offers to sell or procure any medicine;

shall be guilty of an offence and liable to a fine not exceeding level ten or to imprisonment for a period not exceeding five years or to both such fine and such imprisonment.

(3) Any person who tampers with any sample taken in terms of this Act, with intent to defraud or to frustrate the proper testing of the sample, shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

(4) Any person who—

(a) in an application for the registration of any medicine; or

(b) in any statement to the Authority in connection with any medicine; or

(c) in the course of or for the purposes of selling any medicine; or

(d) for the purposes of this Act;

makes any statement which he knows to be misleading or false or which he does not have reasonable grounds for believing to be true, shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

(5) Any person who sells any medicine in a container on or in which he knows or ought reasonably to know there is a false or misleading statement regarding the contents shall be guilty of an offence and liable to a fine not exceeding level twelve or to imprisonment for a period not exceeding two years or to both such fine and such imprisonment.

(6) Any person who, for the purposes of business or trade, publishes any report or certificate made or issued by an inspector or analyst under this Act shall be guilty of an offence and liable to a fine not exceeding level four or to imprisonment for a period not exceeding one month or to both such fine and such imprisonment.

(7) Any person who is not licensed in terms of Part VI and who uses the name pharmacist, pharmacy, chemist, pharmaceutical chemist, chemist and druggist, druggist or pharmaceutist or any name, title, description or symbol indicating or calculated to lead persons to infer that he and additionally, or alternatively, his premises are licensed in terms of Part VI shall be guilty of an offence and liable to a fine not exceeding level ten or to imprisonment for a period not exceeding one year or to both such fine and such imprisonment.

(8) Any person who sells or for gain uses any medicine manufactured, sold or represented as a veterinary medicine for the treatment of any person shall be guilty of an offence and liable to a fine not exceeding level ten or to imprisonment for a period not exceeding one year or to both such fine and such imprisonment.

Section substituted by Act 22 of 2001 with effect from the 20th May, 2002,
but with effect from the 10th September, 2002 being the date on which the scale of all fines in this Act came into force.

68

repealed by Act 22 of 2001 with effect from 20th May, 2002.

69 Special jurisdiction of magistrates courts

amended by Act 5 of 2014 with effect from the 2nd January,2015

Notwithstanding anything to the contrary contained in the Magistrates Court Act [*Chapter 7:10*]—

(a) a magistrate other than a provincial or regional magistrate, shall have special jurisdiction to impose on summary trial or on remittal of the case for trial or sentence by the Prosecutor-General—

(i) a fine not exceeding level eleven; or

amended by Act 22 of 2001 with effect from 10 September, 2002

(ii) imprisonment for a period not exceeding five years; or

(iii) both the penalty specified in subparagraph (i) and the penalty specified in subparagraph (ii);

(b) a provincial magistrate shall have special jurisdiction to impose on summary trial or on remittal of the case for trial or sentence by the Prosecutor-General—

(i) a fine not exceeding level thirteen; or

amended by Act 22 of 2001 with effect from 10 September, 2002

(ii) imprisonment for a period not exceeding ten years; or

(iii) both the penalty specified in subparagraph (i) and the penalty specified in subparagraph (ii);

(c) a regional magistrate shall have special jurisdiction to impose on summary trial or on remittal of the case for trial or sentence by the Prosecutor-General—

(i) a fine not exceeding level fourteen; or

amended by Act 22 of 2001 with effect from 10 September, 2002

(ii) imprisonment for a period not exceeding fifteen years; or

(iii) both the penalty specified in subparagraph (i) and the penalty specified in subparagraph (ii);

for a contravention of this Act.

70 Procedure and evidence

(1) In any criminal proceedings under this Act—

(a) any quantity of a medicine or a substance to which any regulations referred to in paragraph (*b*) of subsection (1) of section *thirty-eight* apply in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken in terms of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample;

(b) any person who is proved to have tampered with a sample shall be deemed to have acted with fraudulent intent unless the contrary is proved;

(c)

repealed by Act 1 of 1996 with effect from 1 August,1997

(d) a certificate stating the result of a test, examination or analysis carried out in terms of section *sixty-six* and purporting to be signed by the analyst who carried out such test, examination or analysis shall be accepted as *prima facie* proof of the facts stated therein;

(e) any statement or entry contained in a book, record or document kept by the owner of a medicine or a substance, device or article to which any regulations referred to in paragraph (*b*) of subsection (1) of section *thirty-eight* apply or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, that owner shall be admissible in evidence against him as an admission of the facts set forth in that statement or entry, unless it is proved that that statement or entry was not made by that owner or by any manager, agent or employee of that owner in the course of his work as manager or in the course of his agency or employment, as the case may be;

(f) if it is proved that a person who was in possession of any medicine in respect of which precautions referred to in subsection (2) of section *thirty-eight* have been prescribed to ensure the safe custody thereof has lost that medicine or has had it stolen, he shall, unless the contrary is proved, be deemed not to have taken the precautions prescribed.

(g) against any person for or in connection with the sale by an employee of any medicine or any substance, device or article to which any regulations referred to in paragraph (*b*) of subsection (1) of section *thirty-eight* apply—

(i) *it shall not be a defence that the employee acted without the authority of the employer; and*

(ii) *any material fact known to the employee shall be deemed to have been known by the employer.*

(2) No prosecution shall be instituted as a result of any test, examination or analysis carried out in terms of section *sixty-six* unless a copy of the certificate of the analyst has, **at least 21 days** before the institution of such prosecution, been handed or transmitted by registered post to the person who is to be the accused.

(3) The court in which a certificate referred to in subsection (2) is adduced in evidence may in its discretion—

(a) cause the person who signed such certificate to be summoned to give oral evidence in the proceedings in question; or

(b) cause written interrogatories to be submitted to that person for reply, and such interrogatories and any reply thereto, purporting to be a reply from that person, shall be admissible in evidence in such proceedings.

70A Registers as evidence

(1) A certificate under the hand of the Director-General—

(a) of the entry of the name of a medicine in the Register kept in terms of section *twenty-seven* shall be *prima facie* evidence that the medicine is registered in terms of this Act;

(b) of the entry of the name of a person in the register referred to in section *fifty-four* shall be *prima facie* evidence that—

(i) *the premises of the person are licensed in terms of this Act—*

A. for the practice or carrying on the business of a pharmacist; or

B. for the manufacture of any medicine; or

C. for the dispensing of any medicine;

on such premises;

or

(ii) *the person is licensed to dispense any medicine in terms of this Act;*

as the case may be;

(c) that the name of a medicine has been cancelled from, or does not appear in, the Register kept in terms of section *twenty-seven* shall be *prima facie* evidence that the medicine is not registered in terms of this Act;

(d) that the name of a person has been cancelled from, or does not appear in, the register referred to in section *fifty-four* shall be *prima facie* evidence that—

(i) *the premises of the person are not licensed in terms of this Act—*

A. for the practice or carrying on the business of a pharmacist; or

B. for the manufacture of any medicine; or

C. for the dispensing of any medicine;

on such premises;

or

(ii) *the person is not licensed to dispense any medicine in terms of this Act;*

as the case may be.

(2) A document purporting to be a certificate under the hand of the Director-General, setting forth the matters referred to in paragraph (*a*), (*b*), (*c*) or (*d*) of subsection (1) or any other records kept by him in terms of this Act shall be admissible in any proceedings on its production by any person as *prima facie* proof of the facts stated therein.

71 Special defence for contravention of section 39

It shall be a sufficient defence for a person charged with the sale of a medicine in contravention of section *thirty-nine* if he proves to the satisfaction of the court that he had no reason to believe that that medicine did not so comply.

72 Act or omission by manager, agent or employee

(1) Whenever any manager, agent or employee of any person, hereinafter called the employer, does or omits to do any act which it would be an offence under this Act for the employer to do or omit to do, then, unless it is proved that—

(a) in doing or omitting to do that act the manager, agent or employee was acting without the connivance or the permission of the employer; and

(b) all reasonable steps were taken by the employer to prevent any act or omission of the kind in question; and

(c) it was not under any condition or in any circumstances within the scope of the authority or in the course of the employment of the manager, agent or employee to do or to omit to do acts, whether lawful or unlawful, of the character of the act or omission charged;

the employer shall be presumed himself to have done or omitted to do that act and shall be liable to be convicted and sentenced in respect thereof.

(2) The fact that the employer issued instructions forbidding any act or omission of the kind in question shall not, of itself, be accepted as sufficient proof that he took all reasonable steps to prevent the act or omission.

(3) Whenever any manager, agent or employee of any such employer does or omits to do an act which it would be an offence under this Act for the employer to do or omit to do, he shall be liable to be convicted and sentenced in respect thereof as if he were the employer.

(4) Any such manager, agent or employee may be so convicted and sentenced in addition to the employer.

73 Preservation of secrecy

(1) Any person who discloses, except—

(a) to the Minister or to any other person for the purposes of the carrying out of his duties or the performance of his functions under this Act; or

(b) to a police officer for the purposes of an investigation or inquiry relating to the enforcement of this Act; or

(c) when required to do so by any court or under any law;

any information acquired by him in the carrying out of any duty or the performance of any function under this Act, in relation to the business or affairs of any other person, shall be guilty of an offence and liable to a fine not exceeding level ten or to imprisonment for a period not exceeding one year.

amended by Act 22 of 2001 with effect from 10 September, 2002

(2) Any person who has acquired information relating to the business or affairs of another person in the course of carrying out any duty or performing any function under this Act, and who uses that information for personal gain, shall be guilty of an offence and liable to a fine not exceeding level ten or to imprisonment for a period not exceeding five years or to both such fine and such imprisonment.

inserted by Act 22 of 2001 with effect from 10 September, 2002

73A Laboratory fees

The Authority may, with the approval of the Minister, levy fees for any analysis, service or thing done by the Laboratory in the course of its functions.

74 Regulations

(1) Subject to subsections (3) and (4), the Minister may by regulation provide for all matters which by this Act are required or are permitted to be prescribed or for which he may provide by regulation in terms of this Act, or which, in his opinion, are necessary or convenient to be provided for in order to carry out or give effect to this Act.

(2) Regulations in terms of subsection (1) may provide for—

(a) persons by whom applications may be made for the registration of any medicine or the licensing of any premises or persons;

Homeopathic Remedies (Repeal) Regulations, 2015. SI 96/2015
Complementary Medicines Regulations, 2015. SI 97/2015

(b) forms to be used, particulars to be furnished and samples and quantities of any medicine to be submitted in connection with an application for the registration of any medicine or the licensing of any premises or persons;

(c) the form of any certificate issued under this Act;

(d) the labelling, packing and sealing of any medicine or any substance, device or article to which any regulations referred to in paragraph (*b*) of subsection (1) of section *thirty-eight* apply and the furnishing of any particulars regarding the use of the medicine, substance, device or article and the manner in which such information shall be furnished;

(e) the methods of sampling, testing and certifying medicines or substances, devices and articles to which any regulations referred to in paragraph (*b*) of subsection (1) of section *thirty-eight* apply;

(f) the terms in which a medicine, other than a registered medicine, shall or shall not be advertised;

(f1) the issue of permits to any person or body engaged in the handling of medicines for any purpose, for gain or otherwise;

(g) the fees payable—

(i) in respect of an application for the registration of a medicine; or

(ii) annually for the retention of the registration of a medicine; or

(iii) annually for the retention of the right to sell an unregistered specified medicine referred to in subsection (2) of section twenty-nine; or

(iv) in respect of the issue or renewal of a licence for premises or persons in terms of Part VI; or

(v) in respect of the temporary renewal of a licence; or

(vi) in respect of the application for authorization to conduct a clinical trial of any medicine; or

(vii) in respect of the issue and renewal of any permit granted in terms of this Act*;*

inserted by Act 1 of 1996 with effect from 1 August,1997

or

(viii) for any other application or thing done in terms of this Act:

inserted by Act 1 of 1996 with effect from 1 August,1997

Provided that the Authority may exempt any person or body from the payment of any fee for good cause shown;

inserted by Act 1 of 1996 with effect from 1 August,1997

(h) the minimum standards, structure and layout of premises, and the quality of service and facilities to be provided in respect of the premises to be licensed;

(i) the tests or examinations that applicants for a licence should be required to take and pass;

(j) the different forms of licences that may be issued;

(k) the regulation and control of clinical trials.

(3) Subject to sections *thirty-eight* and *thirty-nine*, regulations made in terms of subsection (1) may prescribe penalties for contraventions thereof, but no such penalty shall exceed a fine of level seven or imprisonment for a period of six months or to both such fine and such imprisonment.

substituted by Act 22 of 2001 with effect from 10 September, 2002

(4)

repealed by Act 1 of 1996 with effect from 1 August,1997. A consequential amendment to subsection (1) is accordingly required.- Editor.

75 Exemptions

The Authority may, in writing, exempt, subject to such conditions as it may specify, any medicine or substance from the operation of any or all of the provisions of this Act.

substituted by Act 1 of 1996 with effect from 1 August,1997

76 Savings and transitional provisions

The *Third Schedule* shall apply in relation to the succession of the Authority to the former Council and other matters connected with or incidental to the coming into effect of the Drugs and Allied Substances Amendment Act, 1996 on the 1st August 1997.

FIRST SCHEDULE (Section 14)

POWERS OF AUTHORITY

1. To acquire by lease, purchase or otherwise immovable property and to construct buildings thereon.

2. To buy, take in exchange, hire or otherwise acquire movable property, including vehicles, necessary or convenient for the performance of its functions.

3. To maintain, alter and improve property acquired by it.

4. To mortgage or pledge any assets or part of any assets and, with the approval of the Minister, to sell, exchange, let, dispose of, turn to account or otherwise deal with any assets or part of any assets which are not required for the exercise of its functions for such consideration as the Authority may, with the approval of the Minister, determine.

5. To open bank and building society and post office accounts in the name of the Authority and to draw, make, accept, endorse, discount, execute and issue for the purposes of its functions cheques, promissory notes, bills of exchange, bills of lading, securities and other instruments.

6. To insure against losses, damages, risks and liabilities which it may incur.

7. To invest, in such manner and on such security, if any, as the Authority may determine, any funds of the Authority which are not immediately required and to vary or realise any investment so made.

8. To enter into contracts and suretyships or give guarantees in connection with the exercise of its functions and to modify or rescind such contracts or rescind such suretyships or guarantees.

9. With the approval of the Minister, to enter into, renew, cancel or abandon arrangements with any government or authority, local or otherwise, that may seem conducive to the exercise of its functions or any of them and to obtain from such government or authority rights, privileges and concessions which the Authority thinks desirable to obtain and carry out, exercise and comply with such arrangements, rights, privileges and concessions.

10. With the approval of the Minister, to raise loans or borrow money in such amounts and for such purposes and under such conditions as may be approved by the Minister.

11. To establish and administer such funds and reserves as the Authority may consider appropriate or necessary for the proper exercise of its functions.

12. To employ, upon such terms and conditions as the Authority may think fit, such persons as may be necessary for conducting its affairs, and suspend or discharge any such persons.

13. To pay such remuneration and allowances and grant such leave of absence and to make such gifts and pay bonuses and the like to its employees as the Authority thinks fit.

14. Without derogation from section *fourteenA* or the *Second Schedule*, to provide pecuniary benefits for its employees on their retirement, resignation, discharge or other termination of service or in the event of their sickness or injury and for their dependants, and for that purpose to effect policies of insurance, establish pension or provident funds or make such other provision as may be necessary to secure for its employees and their dependants any or all of the pecuniary benefits to which this paragraph relates.

15. With the approval of the Minister, to purchase, take in exchange, hire or otherwise acquire land or dwellings for use or occupation by its employees.

16. To construct dwellings, outbuildings or improvements for use or occupation by its employees on land purchased, taken in exchange, hired or otherwise acquired by the Authority.

17. To sell or let dwellings and land for residential purposes to its employees.

18. With the approval of the Minister, to guarantee loans to its employees or their spouses for the purchase of dwellings or land for residential purposes, the construction of dwellings and the improvement of dwellings or land which are the property of its employees or their spouses.

19. To provide security in respect of loans guaranteed in terms of paragraph 18 by the deposit of securities.

20. With the approval of the Minister, to make loans to any employee of the Authority—

(a) for the purpose of purchasing vehicles, tools or other equipment used by him in carrying out his duties; or

(b) not exceeding three months' salary or wages payable to him, for any purpose;

on such security as the Authority considers adequate.

21. To do anything for the purpose of improving the skill, knowledge or usefulness of its employees, and in that connection to provide or assist other persons in providing facilities for training, education and research and to pay for the aforesaid, where necessary.

22. To provide such services as the Authority considers could properly be provided by the Authority.

23. With the approval of the Minister, to provide financial assistance to any person, association, organization or institution whose activities are such as to be, in the opinion of the Authority, of benefit to the Authority.

24. To grant such scholarships or bursaries as the Authority considers to be in the interests of the Authority, on such terms and conditions as the Authority may fix in any particular case.

25. To do anything which by this Act is required or permitted to be done by the Authority.

26. To do all things that are calculated to facilitate or are incidental or conducive to the performance of the functions of the Authority or the exercise of its powers in terms of this Act or any other law.

27. Generally, to do all such things as may be necessary, conducive or incidental to the exercise of the powers and the performance of the functions of the Authority under this Act or any other enactment.

SECOND SCHEDULE (Section 14A)

PENSION RIGHTS OF STAFF OF AUTHORITY

Interpretation

1. In this Schedule—

"contributor" means an employee of the Authority who is required in terms of section *fourteen A* to contribute to the Consolidated Revenue Fund.

Commencement of pensionable service and grade and classification of contributors

2. Whenever an employee of the Authority is required to contribute in terms of section *fourteen A*, the Public Service Commission shall—

(a) fix the date from which he shall contribute; and

(b) specify the employee's grade and classification in the Public Service for the purpose of determining the rate at which he shall contribute and any other matter relating to the payment of a pension or other benefit to him.

Application to contributors of laws relating to Public Service

3. Subject to paragraphs 9 and 10, the law relating to—

(a) the payment of contributions and arrear contributions in respect of pensions by members of the Public Service; and

(b) the retirement, resignation, discharge and pensionable age of members of the Public Service; and

(c) the payment of pensions and other benefits to members of the Public Service and their dependants; and

(d) the commutation of pensions payable to former members of the Public Service; and

(e) the recall to duty of former members of the Public Service who were required to retire on the grounds of their ill-health or mental or physical infirmity or deficiency;

including the Pensions and Other Benefits Act [*Chapter 16:01*], shall apply, *mutatis mutandis*, in respect of every contributor in accordance with the declaration made in regard to him by the Public Service Commission in terms of subparagraph (b) of paragraph 2, as though his service with the Authority were service with the State and any reference in such law to the Public Service Commission were a reference to the Authority.

Authority to contribute to Consolidated Revenue Fund

4. The Authority shall pay monthly into the Consolidated Revenue Fund such amount as may be determined by the Minister responsible for finance, after consultation with the Authority, in respect of the Authority's contributions towards the pensions benefits of contributors.

Pension contributions to be deducted

5. Any contributions for pension purposes which are payable to the Consolidated Revenue Fund in terms of this Act by an employee of the Authority shall be deducted from the emoluments of the employee concerned and paid by the Authority into the Consolidated Revenue Fund.

Disability benefits

6. Any enactment providing for the payment of compensation in respect of the injury to or death of members of the Public Service shall apply, *mutatis mutandis*, in relation to contributors as though they were members of the Public Service.

Suspension, reduction or forfeiture of pension or gratuity

7. If any employee or former employee of the Authority who becomes entitled to a pension or gratuity or is in receipt of a pension under this Act—

(a) is found by the Authority to have made improper use of or to have disclosed in an improper manner any information which he may have obtained in the course of his employment; or

(b) is found by a competent court to have been guilty of misappropriation of property of the Authority, and such misappropriation would, if it had been discovered before he become entitled to a pension or gratuity, have rendered him liable to discharge or dismissal; or

(c) is found to have made a false statement for the purpose of obtaining a pension, knowing the statement to be false or not having reasonable grounds for believing it to be true; or

(d) refuses to comply with a reasonable request made by the Authority to afford all assistance and information in his power relating to any appointment formerly held or class of duty formerly carried out by him; or

(e) solicits or, without the consent of the Authority, accepts, directly or indirectly, any gift of a pecuniary value after retirement in connection with his service with the Authority;

the Minister may order that any right to any pension or gratuity to which that person has become entitled or the pension of which he is in receipt shall be suspended, reduced or forfeited.

Deduction from pension, gratuity, refund of contributions or other benefits

8. (1) The Minister may authorize the deduction from any pension, gratuity, refund of contributions, commutation of pension or other benefit payable under this Act to an employee of the Authority who has been discharged or dismissed for misconduct of an amount equal to any direct loss which the Authority has sustained by reason of the conduct of the employee on account of which the employee was discharged or dismissed from the service of the Authority.

(2) The Minister may authorize the deduction from any pension, gratuity, refund of contributions or other benefit to which a person or his estate is entitled under this Act of a liquidated amount which that person is liable to pay to the Authority.

(3) To facilitate the recovery of an amount due under this section, the Minister may order the commutation, in accordance with any enactment relating to the commutation of pensions payable to members of the Public Service, of all or part of the pension payable to the member notwithstanding anything to the contrary contained in this Act.

Pensionable emoluments

9. The salary paid to a contributor by the Authority, together with any allowance declared by the Public Service Commission to be pensionable for the purposes of this paragraph, shall be regarded as the pensionable emoluments of the contributor.

Pensions benefits on contributor's discharge or compulsory retirement in certain circumstances

10. If the Authority, without the approval of the Public Service Commission, discharges a contributor or requires him to retire—

(a) on the grounds of his continued ill-health or if he becomes incapable because of mental or physical deficiency or infirmity of efficiently performing his duties; or

(b) owing to the abolition of his post or a reduction in or an adjustment of the organization of the Authority;

and the contributor is, in terms of the law referred to in paragraph 3, entitled to a pension on such discharge or retirement, the pension payable to him shall be calculated as if he had been discharged or required to retire owing to the abolition of his post but in relation to his actual pensionable service.

THIRD SCHEDULE (Section 76)

SAVINGS AND TRANSITIONAL PROVISIONS: DRUGS AND ALLIED SUBSTANCES CONTROL AMENDMENT ACT, 1996

1 In this Schedule—

"former Laboratory" means the Zimbabwe Regional Drug Control Laboratory which was operated by the State immediately before the 1st August, 1997**.**

2 On and after the 1st August, 1997—

(a) all the assets and liabilities which immediately before that date were assets and liabilities of the former Council shall pass by succession to the Authority, which shall have all such functions and obligations in relation to such assets and liabilities as are conferred by this Act in relation to its assets and liabilities;

(b) all the assets and liabilities which immediately before that date were assets and liabilities appertaining to the former Laboratory shall pass by succession to the Authority, which shall have all such functions and obligations in relation to such assets and liabilities as are conferred by this Act in relation to its assets and liabilities;

(c) all bonds, hypothecations, title deeds, documents, charges, agreements, contracts, notes, instruments and working arrangements subsisting immediately before that date in relation to the former Council shall be of full force and effect against or in favour of the Authority and enforceable as fully and effectively as if, instead of the former Council, the Authority had been named therein and had been a party thereto;

(d) all bonds, hypothecations, title deeds, documents, charges, agreements, contracts, notes, instruments and working arrangements subsisting immediately before that date in relation to the former Laboratory shall be of full force and effect against or in favour of the Authority and enforceable as fully and effectively as if, instead of the State, the Authority had been named therein and had been a party thereto;

(e) it shall not be necessary for the Registrar of Deeds to make any endorsement on the title deeds or in his registers in respect of any immovable property or any right or obligation under a mortgage, hypothecation, pledge, bond, note or charge vested in or imposed upon the Authority under this section, but the Registrar of Deeds shall, when so requested in writing by the Authority in relation to any particular such immovable property, mortgage, hypothecation, pledge, bond, note or charge, cause the name of the Authority to be substituted, free of charge, for that of the former Council on the appropriate title deed or other document in the appropriate register;

(f) any proceeding or cause of action pending or existing immediately before that date by or against the former Council may be continued or enforced by or against the Authority as it might have been by or against the former Council immediately before that date;

(g) any proceeding or cause of action against the State in respect of the former Laboratory may be continued or enforced by or against the Authority as it might have been by or against the State immediately before that date.

3 Every member of the Public Service who, immediately before the 1st August, 1997, is employed in the Ministry for which the Minister is responsible and assigned to the former Council or the former Laboratory and whose employment is not terminated with effect from that date shall be transferred, with his consent, on that date to employment with the Authority.

4 A member who is transferred in terms of paragraph 3 shall enjoy conditions of service with the Authority in relation to the following matters which are no less favourable than those enjoyed by him immediately prior to the date of his transfer—

(a) security of tenure;

(b) salary and salary scale;

(c) pension, including commutation of pension;

(d) leave, whether vacation, sick or other leave, and holiday benefits;

(e) acting, overtime and travelling and subsistence allowances;

(f) hours of duty:

Provided that nothing in this subsection shall be construed as precluding a transferred member from waiving any rights conferred by this paragraph by accepting in writing conditions which are less favourable.

5. Members of the former Council who were in office immediately before the 1st August, 1997 shall continue in office as members of the Authority and, unless they vacate their offices earlier in terms of the principal Act, their terms of office shall expire at the end of the period for which they were appointed to the former Council.

6. Any regulation or notice which was made by the Minister in terms of the principal Act and which was in force immediately before the 1st August, 1997 shall continue to have the same force as if it were a regulation or notice, as the case may be, made by the Authority in terms of this Act.

7. Any notice which was made by the Registrar or the former Council and which was in force immediately before the 1st August, 1997 shall continue to have the same force as if it were a notice made by the Director-General or the Authority, as the case may be.

8. Any drug which was registered in terms of this Act before the 1st August, 1997 shall be **deemed to be a medicine** registered in terms of the principal Act.

9. Any drug which was specified by the Minister in terms of section 28 of this Act before the 1st August, 1997 shall be **deemed to be a specified medicine**.

10. Stand number 1753 situated in the township of Salisbury, and also known as 106 Baines Avenue, Harare and Stand numbers 5775-5776 situated in the township of Salisbury and also known as 73 Dunmore Avenue, Queensdale, Harare, shall be transferred with effect from the 1st August , 1997 to the Authority.

11. The Registrar of Deeds shall make such endorsements on the appropriate title deeds and in his registers as may be required by reason of the transfer to the Authority of the property referred to in paragraph 10, and all such transfers shall be exempt from stamp duty, fees of office and other such charges.