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## ACT

To provide for the registration of drugs intended for human use, for the establishment of a Drugs Control Council and for matters incidental thereto.

(Afrikaans text signed by the State President.)  
(Assented to 19th June, 1965.)

**BE IT ENACTED** by the State President, the Senate and the House of Assembly of the Republic of South Africa, as follows:—

### Definitions.

1. (1) In this Act, unless the context otherwise indicates—
  - (i) "advertisement", in relation to any drug, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—
    - (a) appearing in any newspaper or other publication; or
    - (b) distributed to members of the public; or
    - (c) brought to the notice of members of the public in any manner whatsoever,
 which is intended to promote the sale of that drug; and "advertise" has a corresponding meaning; (i)
  - (ii) "analyst" means a person appointed as such under section *twenty-seven*; (xiv)
  - (iii) "appeal board" means the Drugs Control Appeal Board established by section *ten*; (ii)
  - (iv) "approved name", in relation to a drug means the internationally recognized name of such drug or such other name as the council may determine; (ix)
  - (v) "chemist and druggist" means a person registered as such under the Medical Act; (iii)
  - (vi) "council" means the Drugs Control Council established by section *two*; (xvii)
  - (vii) "dental practitioner" means a person registered as a dentist under the Medical Act; (xxi)
  - (viii) "drug" means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—
    - (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or
    - (b) restoring, correcting or modifying any somatic or psychic or organic function in man; (xii)
  - (ix) "inspector" means a person appointed as such under section *twenty-six*; (xi)
  - (x) "label", when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun, means any brand or mark or any written, pictorial or other descriptive matter appearing on or attached to or packed with and referring to any article or the package containing any article; (v)

- (xi) "Medical Act" means the Medical, Dental and Pharmacy Act, 1928 (Act No. 13 of 1928); (xxiv)
- (xii) "medical practitioner" means a person registered as such under the Medical Act; (vii)
- (xiii) "Minister" means the Minister of Health; (xiii)
- (xiv) "package" means anything in or by which any drug is enclosed, covered, contained or packed; (xv)
- (xv) "pathologist" means a person appointed as such under section *twenty-seven*; (xvi)
- (xvi) "pharmacologist", except for the purposes of paragraph (c) of sub-section (1) of section *ten*, means a person appointed as such under section *twenty-seven*; (vi)
- (xvii) "prescribed" means prescribed by or under this Act; (xxiii)
- (xviii) "register", when used as a noun, means the register referred to in section *thirteen*, and when used as a verb, means to enter in such register; (xviii)
- (xix) "registered" means entered in the register; (viii)
- (xx) "registrar" means the Registrar of Drugs appointed under section *twelve*; (xix)
- (xxi) "regulation" means a regulation made and in force under this Act; (xx)
- (xxii) "sell" means sell by wholesale or retail for human use, and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale for such use, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise for such use; and "sale" and "sold" have corresponding meanings; (xxii)
- (xxiii) "this Act" includes any regulations made thereunder; (x)
- (xxiv) "the territory" means the territory of South-West Africa. (iv)

(2) A drug produced either within or outside the Republic shall, notwithstanding the fact that its components are identical to those of any other drug, for the purposes of this Act not be regarded as being the same drug as that other drug if it is not produced by the same manufacturer or presented in the same form as that other drug.

(3) In determining whether or not the registration or availability of a drug is in the public interest, regard shall be had only to the safety, quality and therapeutic efficacy thereof in relation to its effect on the health of man.

Establishment, powers and functions of Drugs Control Council.

2. There is hereby established a council to be known as the Drugs Control Council which may exercise the powers and shall perform the functions conferred upon or assigned to the council by this Act.

Constitution of council.

3. (1) The council shall consist of not less than five or more than eleven members as may from time to time be determined by the State President.

(2) The following persons shall be appointed by the State President as members of the council, namely—

- (a) at least one but not more than two persons who shall be medical practitioners who have a speciality in medicine entered in the appropriate register contemplated in section *fifteen* of the Medical Act;
- (b) at least one person who shall be a medical practitioner engaged in general medical practice;
- (c) at least one person who shall have a special knowledge of the action and application of drugs for human use;

- (d) at least one person who shall be a chemist and druggist;
- (e) at least one person who shall be an officer of the Department of Health; and
- (f) not more than two other persons.

(3) If two or more persons are appointed in terms of paragraph (c) of sub-section (2) at least one of them shall also be a medical practitioner.

Period of office and remuneration of members of the council.

4. (1) A member of the council shall, subject to the provisions of sub-section (3) of section *six*, be appointed for a period of five years.

(2) Any person whose period of office as a member of the council has expired, shall be eligible for reappointment.

(3) The Minister shall give notice in the *Gazette* of the appointment of any member of the council and the date from which his membership commences and, in the case of a member appointed to fill a casual vacancy on the council, the period for which he is appointed.

(4) A member of the council (other than a person who is in the full-time employment of the State) shall receive such remuneration and such allowances in respect of his services as a member of the council or of any committee thereof, as the State President may determine.

Chairman and vice-chairman.

5. (1) One of the members of the council shall be designated by the State President as chairman of the council and another member shall be designated by the State President as vice-chairman to act as chairman during the absence of the chairman.

(2) The vice-chairman, when acting as chairman as provided in sub-section (1), shall have all the powers and discharge all the duties of the chairman.

Disqualifications, vacation of office and filling of vacancies.

6. (1) No person shall be appointed as a member of the council—

- (a) who is an unrehabilitated insolvent;
- (b) who is disqualified under the Medical Act from carrying on his calling, while so disqualified;
- (c) who has a direct or indirect interest in the sale of any drug; or
- (d) who is not a South African citizen permanently resident in the Republic or the territory.

(2) A member of the council shall vacate his office—

- (a) if he becomes subject to any disqualification referred to in sub-section (1);
- (b) if he ceases to hold any qualification necessary for his appointment;
- (c) if he becomes of unsound mind;
- (d) if he is convicted of an offence and is sentenced to imprisonment without the option of a fine; or
- (e) if he has been absent from more than two consecutive meetings of the council without the council's leave.

(3) If the office of any member of the council becomes vacant before the expiration of the period for which he was appointed, the State President may, subject to the applicable provisions of section *three*, appoint another person to hold office for the unexpired portion of the period for which his predecessor was appointed.

(4) For the purposes of paragraph (c) of sub-section (1) a medical practitioner or a chemist and druggist shall not be deemed to have an interest in the sale of any drug by reason only of the fact that—

- (a) in the case of a medical practitioner, he sells the drug in question in the course of carrying on his professional activities as a medical practitioner; or
- (b) in the case of a chemist and druggist, he sells the drug in question in the course of any business carried on under a licence referred to in Item 7 of Part I of the Second Schedule to the Licences Act, 1962 (Act No. 44 of 1962).

Meetings of the council.

7. (1) The first meeting of the council shall be held at a time and place to be fixed by the Minister, and all subsequent meetings shall, subject to the provisions of sub-section (2), be held at such times and places as may be fixed by the council: Provided that the council shall hold at least one meeting in any period of three months and, if at the close of any meeting the council has not fixed the time and place for its next meeting, such time and place shall be fixed by the chairman.

(2) The chairman of the council may at any time call a special meeting of the council to be held at such time and place as he may determine, and shall, upon a written request signed

by not less than three members of the council, call a special meeting thereof to be held within thirty days after the date of receipt of such request, at such time and place as he may determine.

Quorum, majority decision and chairman's casting vote.

8. (1) A majority of all the members of the council shall form a quorum for any meeting of the council.

(2) At all meetings of the council the chairman, or in his absence the vice-chairman, or in the absence of both the chairman and the vice-chairman, some other member of the council chosen by the members present, shall preside.

(3) Save as provided in section *thirty-six*, the decision of a majority of the members of the council present at any meeting thereof shall constitute a decision of the council, and in the event of an equality of votes in regard to any matter, the person presiding at the meeting in question shall have a casting vote in addition to his deliberative vote.

(4) No decision or act done under the authority of the council shall be invalid by reason only of an interim vacancy on the council or of the fact that a person who is disqualified from being a member of the council, or with respect to whose appointment the provisions of this Act have not been observed, sat or acted as a member at the time when the decision was taken or the act was performed or authorized, if the decision was taken or the act was performed or authorized by the requisite majority of the members of the council present at the time who were entitled to sit and act as members.

Appointment of executive committee and other committees.

9. (1) The council may appoint—

(a) from among its members an executive committee the majority of the members of which shall be persons appointed in terms of paragraphs (a) and (c) of sub-section (2) of section *three*; and

(b) subject to the approval of the Minister, such other committees as it may deem necessary, to investigate and report to it on any matter within the purview of the council in terms of this Act.

(2) The executive committee may, subject to the directions of the council, exercise all the powers and perform all the functions of the council during periods between meetings of the council, but shall not have the power, save in so far as the council otherwise directs, to set aside or vary any decision of the council, and any action taken or decision made by the executive committee shall be subject to review at the first ensuing meeting of the council.

(3) The council may appoint such persons, including persons other than members of the council, as it may deem fit, to be members of any committee appointed in terms of paragraph (b) of sub-section (1).

(4) There shall be payable to a member of a committee of the council (other than a member of the council or a person who is in the full-time employment of the State) such allowances, while he is engaged in the carrying out of his duties as a member of such committee, as the Minister may, in consultation with the Minister of Finance, determine.

Establishment of Drugs Control Appeal Board.

10. (1) There is hereby established a board to be known as the Drugs Control Appeal Board, which shall consist of three members to be appointed by the State President, of whom—

(a) one shall be a retired judge or an advocate of the Supreme Court of South Africa, who shall be the chairman of the board;

(b) one shall be a medical practitioner who has a speciality in medicine entered in the appropriate register contemplated in section *fifteen* of the Medical Act; and

(c) one shall be a pharmacologist.

(2) The provisions of section *four* shall *mutatis mutandis* apply in respect of a member of the appeal board.

Disqualifications, vacation of office and filling of vacancies on appeal board.

11. (1) No person shall be appointed as a member of the appeal board—

(a) if he is a member of the council;

(b) if he has at any time served as a member of a committee referred to in paragraph (b) of sub-section (1) of section *nine*;

(c) if he is in the full-time employment of the State;

(d) if he is an unrehabilitated insolvent;

(e) so long as he is disqualified under any law from carrying on his calling;

- (f) if he has a direct or indirect interest in the sale of any drug;
  - (g) if he holds any appointment under section *twenty-seven*; or
  - (h) if he is not a South African citizen permanently resident in the Republic or the territory.
- (2) A member of the appeal board shall vacate his office—
- (a) if he becomes subject to any disqualification referred to in sub-section (1);
  - (b) if he ceases to hold any qualification necessary for his appointment;
  - (c) if he becomes of unsound mind;
  - (d) if he is convicted of an offence and is sentenced to imprisonment without the option of a fine; or
  - (e) if he has been absent from more than two consecutive meetings of the appeal board without the appeal board's leave.

(3) If the office of any member of the appeal board becomes vacant before the expiration of the period for which he was appointed, the State President may, subject to the applicable provisions of section *ten*, appoint another person to hold office for the unexpired portion of the period for which his predecessor was appointed.

(4) For the purposes of paragraph (f) of sub-section (1) a medical practitioner shall not be deemed to have an interest in the sale of any drug by reason only of the fact that he sells the drug in question in the course of carrying on his professional activities as a medical practitioner.

Appointment of Registrar of Drugs.

12. (1) The Minister may, subject to the laws governing the public service and after consultation with the council, appoint an officer to be styled the Registrar of Drugs who shall perform the functions and carry out the duties assigned to or imposed upon the registrar by or under this Act and such other functions and duties as may from time to time be assigned to or imposed upon him by the Minister or the Secretary for Health.

(2) The registrar shall also act as secretary of the council.

Drugs register.

13. The registrar shall keep in the prescribed form a register to be known as the drugs register, in which he shall register all drugs the registration of which has been approved by the council, and in which he shall enter all such particulars in regard to such drugs as are required by this Act to be entered therein.

Prohibition on sale of drugs which are not registered.

14. (1) Save as provided in this section or section *twenty-one*, no person shall sell any drug unless it is registered.

(2) In the case of a drug which was available for sale in the Republic or the territory immediately prior to the commencement of any regulation promulgated under paragraph (c) of sub-section (1) of section *thirty-five* which is applicable to such drug, the provisions of sub-section (1) shall come into operation—

- (a) if no application for registration of such drug is made within the period of six months immediately succeeding the commencement of such regulation, on the expiration of that period; or
- (b) if application for the registration of such drug is made within the said period, on the date one month after the date on which a notice in respect of such drug is published in the *Gazette* in terms of sub-section (1) of section *fifteen* or paragraph (a) of sub-section (1) of section *seventeen*.

(3) The provisions of sub-section (1) shall not apply in respect of the sale of any drug compounded by a medical practitioner or a chemist and druggist if such drug does not contain any component the sale of which is prohibited by this Act or any component in respect of which an application for registration has been rejected and is not and has not been advertised.

(4) The provisions of sub-section (3) shall, with effect from the date upon which regulations promulgated under paragraph (c) of sub-section (1) of section *thirty-five* come into operation

in relation to all drugs, not apply to any drug unless the active components of such drug have been registered under this Act.

Registration of drugs.

15. (1) Every application for the registration of a drug shall be submitted to the registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant drug and by the prescribed registration fee.

(2) The registrar shall as soon as possible after the receipt by him of any such application submit the application together with any particulars and samples which accompanied the application to the council for consideration and shall simultaneously inform the applicant in writing that the application has been so submitted.

(3) (a) If after consideration of any such application and after any investigation or enquiry which it may consider necessary the council is satisfied that the drug in question is suitable for the purpose for which it is intended and complies with the prescribed requirements and that registration of that drug is in the public interest, it shall approve of the registration thereof.

(b) If the council is not so satisfied it shall cause the applicant to be notified in writing of the reasons why it is not so satisfied and cause the applicant to be informed that he may within a period of one month after the date of the notification furnish the registrar with his comments on the council's reasons for not being so satisfied.

(c) If no such comments are submitted by the applicant within the said period, or if after consideration of any comments so submitted the council is still not satisfied as aforesaid, it shall reject the application.

(4) When the council has approved of the registration of any drug the registrar shall register that drug and shall enter in the register such particulars in regard to the drug as are required by this Act to be so entered and shall issue to the applicant a certificate of registration in the prescribed form in respect of that drug.

(5) Every drug shall be registered under its approved name.

(6) The registrar shall allocate to every drug registered under this Act a registration number which shall be recorded in the register opposite the name of such drug and which shall be stated in the certificate of registration issued in respect of such drug.

(7) Any registration under this section may be made subject to such conditions as may with due regard to the succeeding provisions of this section be determined by the council.

(8) No condition shall be imposed under sub-section (7) whereby the sale of the drug in question by any person other than a chemist and druggist is prohibited or until after the applicant has in writing been notified by the registrar that the imposition of such condition is contemplated and invited to submit written representations to the council in regard to the matter.

(9) If no such representations are lodged with the registrar by the applicant concerned within a period of one month after the receipt by him of any notification referred to in sub-section (8), or if after consideration of any such representations the council is still of the opinion that the condition in question should be imposed, the council shall direct the registrar to register the relevant drug subject to the said condition.

(10) Notice of the rejection of an application under this section in respect of a drug referred to in sub-section (2) of section *fourteen* shall be given in the *Gazette* by the registrar—

(a) if no appeal is lodged against the rejection within the period prescribed in section *twenty-four*, as soon as possible after the expiration of that period; or

(b) if any appeal so lodged is dismissed, as soon as possible after the decision dismissing the appeal has been given.

(11) The registrar shall within fourteen days after the date of expiry of the appropriate period referred to in sub-section (2) of section *fourteen* publish in the *Gazette* the prescribed particulars in respect of all applications for registration received by him prior to such date.

Cancellation of registration.

16. (1) If the council—

- (a) is of the opinion that any person has failed to comply with any condition subject to which any drug has been registered; or
- (b) is of the opinion that any drug does not comply with any prescribed requirement; or
- (c) is of the opinion that it is not in the public interest that any drug shall be available to the public,

the council shall cause notice in writing to be given accordingly by the registrar to the person by whom or on whose behalf application for the registration of that drug was made.

(2) Any such notice shall specify the grounds on which the council's opinion is based, and shall indicate that the person to whom it is directed may within one month after receipt thereof submit to the registrar any comments he may wish to put forward in connection with the matter.

(3) If no such comments are so submitted, or if after consideration of any comments so submitted the council is of the opinion that the registration of the drug in question should be cancelled, the council may direct the registrar to cancel the registration thereof.

Notification of registration or cancellation of registration in *Gazette*.

17. (1) The registrar shall give notice in the *Gazette* of the registration or cancellation of the registration of any drug in terms of this Act, and shall in such notice specify—

- (a) in the case of a registration of any drug, the name under which such drug is registered, the name of the manufacturer thereof, the number allocated to it in terms of section *fifteen* and the conditions (if any) subject to which it is registered;
- (b) in the case of a cancellation of the registration of any drug, the name under which such drug was registered, the name of the manufacturer and the number which was allocated to it in terms of section *fifteen*.

(2) Any notice of registration required to be given under sub-section (1) in respect of any drug referred to in sub-section (2) of section *fourteen* which by reason only of the provisions of sub-section (2) of section *one* is not regarded as being the same drug as any other drug so referred to, shall appear in the *Gazette* simultaneously with any notice so required to be given in respect of that other drug.

Name under which drug is registered and number to appear on labels.

18. (1) No person shall sell any drug registered under this Act unless the package in which such drug is sold bears a label stating—

- (a) the approved name of that drug, immediately followed by the number allocated thereto under section *fifteen*, which shall, if any trade name or brand name (not being such approved name) appears on the label, appear immediately above such trade name or brand name and shall be in letters not less than half the size of the letters in which such trade name or brand name appears and shall in all other respects be not less conspicuous than such trade name or brand name; and
- (b) if the approved name is a trade name or brand name, the active components of such drug by weight or by volume or by unit immediately before or after the said approved name.

(2) No person shall in writing advertise any such drug for sale, unless—

- (a) the approved name of such drug, immediately followed by the number allocated thereto in terms of section *fifteen*, is stated in the advertisement, and (if the trade name or brand name, not being such approved name, of the drug is also stated in the advertisement) appears immediately above such trade name or brand name where it is used for the first time and is in letters not less than half the size of the letters in which such trade name or brand name appears and is in all other respects not less conspicuous than such trade name or brand name; and

(b) where the approved name of such drug is also the trade name or brand name thereof, the number allocated thereto appears immediately after such name where it is used for the first time, and the names, as determined by the council, of the active components thereof and the weight or volume or number of units of such components are stated immediately before such name or after such number.

(3) The provisions of sub-section (1) shall not apply in respect of the sale of any drug—

- (a) sold by a medical practitioner for the treatment of a particular person and supplied by such medical practitioner to or on behalf of such person; or
- (b) sold by a chemist and druggist for the treatment of a particular person and supplied to or on behalf of such person by such chemist and druggist in accordance with a direction given by a medical practitioner; or
- (c) if such drug forms a portion of the original contents of a package which is labelled in accordance with the provisions of this Act and such drug is taken by a chemist and druggist from such package and is sold by such chemist and druggist for the treatment of a particular person and is supplied to or on behalf of such person in a package which bears a label stating the name and address of such chemist and druggist, the number allocated to such drug under section *fifteen*, directions in regard to the manner in which such drug should be used and the name of the person for whose treatment such drug is sold.

Prohibition on sale of drugs which do not comply with prescribed requirements and furnishing of information regarding drugs to the council.

19. (1) No person shall sell any drug unless it complies with the prescribed requirements.

(2) The council may by notice in writing require any person who manufactures or sells or administers or prescribes any drug or on whose direction any drug is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his possession or which such person is in a position to obtain regarding such drug.

(3) The council may, if so requested by any person to whom a notice under sub-section (2) is addressed, extend the period stipulated in such notice.

Publication or distribution of false advertisements concerning drugs.

20. (1) No person shall—

- (a) publish or 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 any drug; or
- (b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any drug is other than that stated by the council in terms of sub-paragraph (ii) of paragraph (a) of section *twenty-two* or state or suggest that any drug should be used for a purpose or under circumstances or in a manner other than that stated by the council in terms of sub-paragraph (iii) of paragraph (a) of that section.

(2) It shall be a sufficient defence in any prosecution for an offence under paragraph (a) of sub-section (1) if it is proved to the satisfaction of the court that the accused, not being a person selling the drug 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 registrar or an inspector or a member of the South African Police to furnish the name and address of the person at whose instance the advertisement was published, distributed or so brought to the notice of the public.

Council may authorize sale of unregistered drug for certain purposes.

21. (1) The council may in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of any particular drug which is not registered.



(2) Any drug sold in pursuance of any authority granted under sub-section (1) may be used for such purposes and in such manner and during such period as the council may in writing determine.

(3) The council may at any time by notice in writing withdraw any authority granted in terms of sub-section (1) if effect is not given to any determination made in terms of sub-section (2).

Council to furnish certain information to medical and dental practitioners and chemists and druggists.

22. The council shall, subject to the approval of the Secretary for Health, in such manner as it considers most suitable—

- (a) as soon as practicable after any drug has been registered, inform medical practitioners, dental practitioners, chemists and druggists and the person who applied for the registration of such drug—
- (i) of the name and number under which such drug is registered and the conditions, if any, subject to which such drug is registered;
  - (ii) of the therapeutic efficacy and effect of such drug;
  - (iii) of the purpose for which, the circumstances under which and the manner in which such drug should be used; and
  - (iv) regarding any other matter concerning such drug which, in the opinion of the council, may be of value to them;
- (b) as soon as practicable after the registration of any drug has been cancelled in terms of section *sixteen*, inform medical practitioners, dental practitioners, chemists and druggists and the person who applied for the registration of such drug of the cancellation of such registration.

Disposal of undesirable drugs.

23. (1) If the council is of the opinion that it is not in the public interest that any drug 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 any person, to return any quantity of such drug which he has in his possession to the manufacturer thereof or (in the case of any imported drug) to the importer concerned or to deliver or send it to any other person designated by the council.

(2) The council may by notice in writing direct any manufacturer or importer of any such drug who has in his possession any quantity thereof (including any quantity returned, delivered or sent to him in pursuance of a direction under sub-section (1)), or any other person to whom any quantity of such drug has been so returned, delivered or sent, to deal with or dispose of that quantity in such manner as the council may determine.

(3) No person shall sell any drug which is the subject of a notice under sub-section (1) which has not been set aside on appeal.

Appeals.

24. (1) Any person who is aggrieved by any decision of the council may appeal against such decision to the appeal board.

(2) (a) Any such appeal shall be lodged within one month after the date of the decision appealed against and shall be accompanied by written arguments and explanations of the grounds of appeal.

(b) The appellant may appear before the appeal board in person or through a representative and may tender evidence and submit any arguments or explanations in support of any written arguments or explanations submitted by him.

(3) The operation of any decision of the council which is the subject of an appeal under sub-section (1) (not being a decision contemplated in sub-section (1) of section *twenty-three*) shall be suspended pending a decision on the appeal.

(4) The decision of the appeal board on any appeal lodged with it under this section shall be final and shall be deemed to be a decision of the council.

Privileges of council and committees.

25. No legal proceedings shall lie against the council or any committee appointed under sub-section (1) of section *nine* or any member of the council or of any such committee in respect of any act done by the council or any such committee in the exercise of its powers or the performance of its functions under this Act.

Appointment of inspectors.

26. (1) The Minister may, subject to the laws governing the public service, appoint such inspectors, who shall be officers of the Department of Health, as he may consider necessary for the proper enforcement of this Act.

(2) Every inspector shall be furnished with a certificate signed by the registrar and stating that he has been appointed as an inspector under this Act.

(3) An inspector shall, before he exercises or performs any power or function under this Act, produce and exhibit to any person affected thereby, the certificate referred to in sub-section (2).

Appointment of analysts, pharmacologists and pathologists.

27. (1) The Minister may appoint such analysts, pharmacologists and pathologists as he may consider necessary for the proper enforcement of this Act.

(2) Every appointment made under sub-section (1) shall be notified in the *Gazette*.

Powers of inspectors.

28. (1) An inspector may at all reasonable times—

(a) enter upon any premises, place, vehicle, vessel or aircraft at or in which there is or is on reasonable grounds suspected to be any drug;

(b) inspect any drug, or any book, record or document found in or upon such premises, place, vehicle, vessel or aircraft;

(c) seize any such drug, 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 drug as he may consider necessary for the purpose of testing, examination or analysis in terms of the provisions of this Act.

(2) Any sample taken in terms of paragraph (d) of sub-section (1) shall be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such drug, 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 such person or such witness be divided into three parts, each of which shall forthwith be fastened up and sealed and suitably labelled or marked in such manner as its nature may permit. One part shall then be transmitted to an analyst, pharmacologist or pathologist together with a certificate in the prescribed form signed by such inspector. The second part, together with a copy of the aforesaid certificate, shall be handed or transmitted by registered post to the owner or seller of such drug or his agent. The third part shall be retained by the inspector.

(3) The analyst, pharmacologist or pathologist to whom one part of a sample has been transmitted in terms of the provisions of sub-section (2) 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.

(4) The owner of the drug from which the sample was taken may claim from the Secretary for Health an amount equal to the market value thereof.

Offences.

29. Any person who—

(a) obstructs or hinders any inspector in the exercise of his powers or the carrying out of his duties under this Act; or

- (b) contravenes or fails to comply with the provisions of sub-section (1) of section *fourteen* or section *eighteen*; or
  - (c) contravenes the provisions of sub-section (1) of section *nineteen* or fails to comply with a notice issued under sub-section (2) of that section; or
  - (d) contravenes the provisions of sub-section (1) of section *twenty*; or
  - (e) contravenes or fails to comply with any condition imposed under sub-section (7) of section *fifteen*; or
  - (f) fails to comply with any direction given under section *twenty-three* or contravenes the provisions of sub-section (3) of that section; or
  - (g) with fraudulent intent tampers with any sample taken in terms of this Act; or
  - (h) makes any false or misleading statement in connection with any drug—
    - (i) in an application for the registration thereof; or
    - (ii) in the course of the sale thereof; or
  - (i) sells any drug upon the container of which a false or misleading statement in connection with the contents is written; or
  - (j) for purposes of business or trade makes use of any report or certificate made or issued by an inspector, analyst, pharmacologist or pathologist under this Act,
- shall be guilty of an offence.

**Penalties.**

30. (1) Any person who is convicted of an offence referred to in section *twenty-nine* shall be liable—

- (a) on a first conviction, to a fine not exceeding five hundred rand or, in default of payment of such fine, to imprisonment for a period not exceeding six months; and
- (b) on a second or subsequent conviction, to a fine not exceeding one thousand rand or to imprisonment for a period not exceeding twelve months or to both such fine and such imprisonment.

(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any drug in respect of which the offence has been committed to be forfeited to the State.

(3) Any drug forfeited under this Act shall be destroyed or otherwise dealt with as the Minister may direct.

**Procedure and evidence.**

31. (1) In any criminal proceedings under this Act—

- (a) any quantity of a drug in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions 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 any sample shall be deemed to have acted with fraudulent intent unless the contrary is proved;
- (c) a certificate stating the result of a test, examination or analysis carried out in terms of the provisions of section *twenty-eight* and purporting to be signed by the analyst, pharmacologist or pathologist who carried out such test, examination or analysis, shall be accepted as *prima facie* proof of the facts stated therein;
- (d) any statement or entry contained in any book, record or document kept by any owner of a drug, 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, such 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 such owner, or by any manager, agent or employee of such owner in the course of his work as manager, or in the course of his agency or employment.

(2) No prosecution shall be instituted as a result of any test, examination or analysis carried out in terms of the provisions of section *twenty-eight* unless a copy of the analyst's, pharmacologist's or pathologist's certificate has, at least twenty-one 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 any such certificate is adduced in evidence may in its discretion cause the person who signed such certificate to be summoned to give oral evidence in the proceedings in question or may cause written interrogatories to be submitted to him for reply, and such interrogatories and any reply thereto, purporting to be a reply from such person, shall be admissible in evidence in such proceedings.

Special defences  
in case of  
prosecutions.

32. It shall be a sufficient defence for a person charged with the sale of any drug in contravention of the provisions of section *nineteen* if he proves to the satisfaction of the court—

- (a) that he purchased such drug from a person residing in the Republic who had furnished him with a written warranty that such drug complied with the prescribed requirements; and
- (b) that he had no reason to believe that such drug did not so comply.

Act or omission  
by manager,  
agent or employee.

33. (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; and the fact that he 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.

(2) 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.

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

Preservation of  
secrecy.

34. Any person who discloses, except to the Minister or to any other person for the purpose of the carrying out of his duties or the performance of his functions under this Act or 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 on conviction to a fine not exceeding one thousand rand or to imprisonment for a period not exceeding twelve months.

Regulations.

35. (1) The council may, with the approval of the Minister, make regulations—

- (a) prescribing the persons by whom application may be made for the registration of any drug;
- (b) prescribing the forms which shall be used for any application for the registration of any drug and the particulars which shall be furnished with any such application (including particulars regarding the method by which the drug in question or any component of such drug is manufactured and the premises in which such drug or any such component is manufactured);
- (c) providing for the provisions of sub-section (1) of section *fourteen* to come into operation in terms of sub-section (2) of that section in respect of any specified drugs or classes or categories of drugs;
- (d) prescribing the samples of any drug and the quantity thereof which shall accompany any application for the registration of a drug;

- (e) prescribing the form in which the drugs register shall be kept and the particulars which shall be entered therein in respect of any registered drug;
- (f) prescribing the form of any certificate of registration of any drug;
- (g) prescribing the manner in which any package containing any drug shall be labelled, packed or sealed;
- (h) prescribing the particulars in regard to the use thereof which shall be furnished with any drug sold, and the manner in which such particulars shall be furnished;
- (i) prescribing the particulars which shall appear in any advertisement relating to any drug;
- (j) prescribing the requirements with which any drug or any component thereof shall comply in regard to composition, therapeutic suitability and effect, purity or any other property;
- (k) prescribing the particulars which shall be published in the *Gazette* in respect of any application for registration referred to in sub-section (11) of section *fifteen*; and
- (l) prescribing the procedure at meetings of the council and of the appeal board and of any committee appointed under section *nine* (including the quorum in the case of committees) and the manner in which meetings of the appeal board and of any such committee shall be called.

(2) The council shall, not less than three months before any regulation is made under sub-section (1), cause the text of such regulation to be published in the *Gazette* together with a notice declaring its intention to make that regulation and inviting interested persons to furnish it with any comments thereon or any representations they may wish to make in regard thereto.

(3) The provisions of sub-section (2) shall not apply in respect of—

- (a) any regulation made by the council which, after the provisions of that sub-section have been complied with, has been amended by the council in consequence of comments or representations received by it in pursuance of the notice issued thereunder; or
- (b) any regulation in respect of which the Minister is, after consultation with the council, of the opinion that the public interest requires it to be made without delay.

(4) The Minister may, after consultation with the council, make regulations—

- (a) prescribing the methods in accordance with which samples may be taken under this Act and the form of the certificates to be issued by inspectors in respect of such samples;
- (b) prescribing the methods to be employed and the form of the certificates to be issued in connection with the testing, examination or analysis of samples taken under this Act;
- (c) prescribing the fee (not exceeding one hundred rand) to be paid to the registrar in respect of the registration of a drug; and
- (d) generally for the efficient carrying out of the objects and purposes of this Act.

(5) No regulation shall be made under paragraph (c) of sub-section (4) except in consultation with the Minister of Finance.

(6) The provisions of sub-sections (2) and (3) shall *mutatis mutandis* apply to any regulation made by the Minister under sub-section (4).

(7) Regulations may be made under this section in respect of particular drugs or classes or categories of drugs or in respect of drugs other than particular classes or categories of drugs, and different regulations may be so made in respect of different drugs or different classes or categories of drugs.

(8) Any regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith not exceeding a fine of two hundred rand or imprisonment for a period of three months.

Exclusion of any drug from operation of Act.

36. The Minister may, on the unanimous recommendation of the members present at any meeting of the council, by notice in the *Gazette* exclude, subject to such conditions as

he may determine, any drug from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice.

Drugs manufactured for export.

37. Notwithstanding anything to the contrary in this Act contained, the provisions of this Act shall not apply in respect of any drug or any quantity of any drug which is manufactured in or imported into the Republic solely for the purpose of export from the Republic and is not used or disposed of for use in the Republic and in respect of which the council has granted a certificate that it is satisfied in regard to its quality, purity and safety.

Operation of Act in relation to other laws.

38. The provisions of this Act shall be in addition to and not in substitution for any other law which is not in conflict with or inconsistent with this Act.

Application of Act in South-West Africa.

39. This Act and any amendment thereof shall apply also in the territory (including the Eastern Caprivi Zipfel referred to in sub-section (3) of section *three* of the South-West Africa Affairs Amendment Act, 1951 (Act No. 55 of 1951)) and in relation to all persons in the portion of the territory known as the "Rehoboth Gebiet" and defined in the First Schedule to Proclamation No. 28 of 1923 of the territory.

Short title and commencement.

40. This Act shall be called the Drugs Control Act, 1965, and shall come into operation on a date to be fixed by the State President by proclamation in the *Gazette*.