REPUBLIC OF SOUTH AFRICA

SOUTH AFRICAN MEDICINES AND MEDICAL DEVICES REGULATORY AUTHORITY BILL

(As amended by the Portfolio Committee on Health (National Assembly))

(MINISTER OF HEALTH)

[B 114B—98]

REPUBLIEK VAN SUID-AFRIKA

WETSONTWERP OP DIE SUID-AFRIKAANSE MEDISYNE EN MEDIESE TOESTELLE REGULERENDE OWERHEID

(Soos gewysig deur die Portefeuljekomitee oor Gesondheid (Nasionale Vergadering))

(MINISTER VAN GESONDHEID)

[W 114B—98]

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GENERAL EXPLANATORY NOTE:

[ ] Words in bold type in square brackets indicate omissions from existing enactments.

Words underlined with a solid line indicate insertions in existing enticements.

BILL

To provide for the regulation and registration of medicines intended for human and for animal use; for the regulation and registration of medical devices; for the establishment of the South African Medicines and Medical Devices Regulatory Authority; for the control of orthodox medicines, complementary medicines, veterinary medicines, scheduled substances and medical devices; for the control of persons who may compound and dispense orthodox medicines, complementary medicines and veterinary medicines; for the repeal of the Medicines and Related Substances Control Act, 1965; the amendment of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 and for matters incidental thereto.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:—

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CHAPTER I

INTRODUCTORY PROVISIONS

Definitions

1. In this Act, unless the context indicates otherwise– -

"advertisement", in relation to any orthodox medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

(a) appearing in any newspaper, magazine, pamphlet 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 or orthodox medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance; and "advertise" has a corresponding meaning

"adverse event, or adverse drug event" means an unintended deleterious effect of a medicine when used in usual dosage;

"analyst" means an analyst to whom authority has been granted under section 37;

"approved name" in relation to a medicine, means the international nonproprietary name (INN) of such medicine or, where no such name exists such other name as the Board may determine, not being a brand or trade name registered in terms of the Trade Marks Act, 1993 (Act No. 194 of 1993);

"Appeal Board"' means the Appeal Board appointed in terms of section 26(1);

"audit committee" means the audit committee appointed in terms of section 19(3);

"Auditor-General" means the person who in terms of item 20 of Schedule 6 to the Constitution continues to function and to hold office under the Auditor-General Act, 1995 (Act No 12 of 1995) or is appointed as such in terms of section 193 of the Constitution:

"Authority" means the South African Medicines and Medical Devices Regulatory Authority established by section 2;

"Board" means the Board appointed in terms of section 6(1);

"Chief Executive officer'" means the Chief Executive Officer appointed in terms of section **16(2);**

"complementary medicine" means any substance or mixture of substances, which—

(a) originates from a plant, mineral, or animal, and which may be, but is not limited to, being classified as herbal, homeopathic, ayurvedic or nutritional; and

(b) is used or intended to be used for, or manufactured or sold for use in, or purported to be useful in, complementing the healing power of a human or animal body or for which there is a claim regarding its effect in complementing the healing power of a human or animal body in the treatment, modification, alleviation or prevention of disease, abnormal physical or mental state or the symptoms thereof in a human being or animal: and

(c) is used in, but not limited to, the disciplines of Western herbal, African traditional, traditional Chinese, Homeopathy, Ayurveda, Unani, Antroposophy, Aromatherapy and Nutritional supplementation; or

(d) because of its origin, intended use or use in a discipline, is determined by the Authority, by notice in the Gazette, to be a complementary medicine;

"Constitution" means the Constitution of the Republic of South Africa, 1996 (Act No 108 of 1996);

"day" means calendar day;

"dentist" means a person registered as such under the Medical, Dental and Supplementary Health Service Professions Act, 1974 (Act No, 56 of 1974):

"department" means the Department of Health, or in relation to a matter concerning veterinary medicines, means the Department of Health and the Department of Agriculture;

"Director-General" means the Director-General of Health or, in relation to a matter concerning veterinary medicines, means the Director-General: Health acting in consultation with the Director-General of Agriculture;;

"dispensing" means the interpretation and evaluation of a prescription, the selection, manipulation of the medicine, the labelling and supply of medicines in an appropriate container and the provision of information and instructions to ensure the safe and effective use of a medicine by a patient, and "dispense" has a corresponding meaning;

"export" includes deliver or supply within the Republic for dispatch to any destination outside the Republic;

"hospital" means any institution established as a hospital or a nursing home or registered as such in terms of any law;

"immediate container", in relation to an orthodox medicine, complementary medicine, veterinary medicine, or scheduled substance, means a container which is in direct contact with the medicine, complementary medicine, veterinary medicine or substance;

"immediate family member", in relation to any person, means that person's spouse, parent, child, brother or sister;

"inspector" means a person designated as such under section 40;

"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;

"manufacture" means all operations including purchasing of material, processing, production, packaging, quality control, release and storage of medicinal products and related control;

'<medical device" or "device" means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent or any other article, whether used alone or in combination, including software necessary for its proper application used for or purporting to be suitable for use or manufactured or sold for use in or on a human or animal body-

(i) in the diagnosis. prevention, monitoring, treatment or alleviation of disease: or

(ii) in diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; or

(iii) in investigation, replacement or modification of the anatomy or of a physiological process; or

(iv) in the diagnosis of pregnancy, or the control of conception or termination of pregnancy;

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

"medical practitioner" means a person registered. as such under the Medical, Dental and Supplementary Health Service Professions Act, 1974 and includes an intern registered under that Act;

"Medicines Act" means the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965);

"Minister" means the Minister of Health or in relation to a matter concerning veterinary medicines, means the Minister of Health acting in consultation with the Minister of Agriculture;

"orthodox medicine" or "medicine" means any substance or "mixture of substances intended to be used by, or administered t], human beings for any of the following therapeutic purposes:

(a) treating, preventing or alleviating symptoms of disease, abnormal physical or mental state or the symptoms thereof;

(b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;

(c) otherwise preventing or interfering with the normal operation of physiological function, whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of that function;

"nurse" means a person registered as a nurse under the Nursing Act, 1978 (Act No. 50 of 1978);

"package" means anything in or by which any medicine, complementary. veterinary medicines or scheduled substance is enclosed, covered, contained or packed;

"pathologist" means a pathologist to whom authority has been granted under section 37;

"pharmacist", means a person registered as such under the Pharmacy Act, 1974 (Act No. 53 of 1974);

"pharmacist intern", means a person registered as such under the Pharmacy Act, 1974;

"pharmacy support personnel" means the various categories of support personnel as prescribed and registered as such under the Pharmacy Act 1974 and includes a pharmacist's assistant registered under the Act;

"pharmaco-vigilance" means the active collection, detection, assessment and prevention of adverse drug events;

"practitioner", means a person registered as such under the Chiropractors, Homeopaths and Allied Health Service Professions Act, 1982 (Act No 63 of 1982);

"prescribe" means prescribed by regulation;

"register", when used as a noun. means the register referred to in section 24, and when used as a verb, means enter in the register;

"regulation". means a regulation made under this Act;

"Scheduled substance", means any medicine or other substance prescribed under section 31;

"sell" means sell by wholesale or retail and includes import, offer, advertise, keep, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, or exchange or supply or dispose of to any person whether for a consideration or otherwise; and "sale" and "sold" have corresponding meanings;

"spouse". includes a person with whom one lives a if they were married or with whom one habitually cohabits:

"stock remedy". means any substance or mixture of substances registered as a stock remedy in terms of the Stock Remedies Act;

"Stock Remedies Act", means the Fertilizers, Far n Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No 36 of 19⁄ 7);
"this Act" includes the regulations;
"veterinarian" means a person registered or dee ned to be registered under the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 39 of 1982);
"veterinary medicine" means any substance or m xture of substances intended or manufactured for use in connection with ani nals for diagnosis, treatment, alleviation, modification or prevention of disease or unhealthy physical condition, for the improvement of growth, production or working capacity, for the lasting capacity of carcasses, for curing, correcting or modifying behaviour or for humane euthanasia, but does not include feedstuffs.

CHAPTER II

SOUTH AFRICAN MEDICINES AND MEDICAL DEVICES REGULATORY AUTHORITY

Establishment of South African Medicines and Medical Devices Regulatory Authority

2. (1) The South African Medicines and Medical Devices Regulatory Authority is hereby established.

(2) The Authority is a juristic person.

(3) The Authority must be independent and impartial in the performance of its functions.

(4) *(a)* The Minister may by notice in the *Gazette* issue policy consistent with the objects mentioned in section 5.

(b) The Minister must, before policy contemplated in paragraph *(a)* is issued—

(i) consult the Authority; and

(ii) in order to obtain a view of interested persons, cause the text of such policy to be published in the *Gazette* together with a notice declaring the Minister's intention to issue that policy and invite interested persons to lodge written representations in relation to the policy in the manner specified in such notice within 30 days from the date of the notice or such other period as the Minister may determine.

(c) Paragraph *(b)* does not apply in respect of any alteration by the Minister of a policy in consequence of comments or representations received by the Minister pursuant to consultation or publication in terms of that paragraph.

(d) A policy issued under this section maybe amended, withdrawn or substituted by the Minister, and this section applies, with the necessary changes required by the context, in relation to any such amendment, withdrawal or substitution.

(5) The management of the affairs of the Authority must be conducted by the Board.

(6) The Board must manage the affairs of the Authority in accordance with the policies determined by the Minister.

(7) The Authority must perform its functions in accordance with this Act.

(8) The Board may, and at the request of the Minister must, provide the Minister with advice on any matter dealt with by this Act.

Vesting of certain rights and obligations in respect of property in Authority

3. All the rights and obligations of the State and of the Medicines Control Council, in respect of all the movable property that was immediately prior to the commencement of

this Act used exclusively in connection with the work performed by the officers and employees of the State for the purposes of the functions of the Medicines Control Council and in the case of stock remedies, the Registrar of Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies vest, without any liability to pay compensation, in the Authority.

Vesting of certain State property in Authority

4. All movable State property that was immediately prior to the commencement of this Act used exclusively for the purposes and functions of the Medicines Control Council, the Directorate: Medicines Administration and in the case of stock remedies, the Registrar of Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies vest, without any liability to pay compensation, in the Authority.

Objects and functions of South African Medicines and Medical Devices Regulatory Authority

5. The primary object of the South African Medicines and Medical Devices Regulatory Authority is, subject to the provisions of this Act, to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, complementary medicines, veterinary medicines, clinical trials and medical devices and related matters in the public interest, and or that purpose it must—

(a) ensure the efficient, effective and ethical evaluation and registration of medicines, complementary medicines, veterinary medicines and devices that meet defined standards of quality, safety ant! efficacy;

(b) ensure that the process of evaluating and registering medicines, complementary medicines, veterinary medicines and devices is, subject to this Act, transparent, fair, objective and concluded timeously;

(c) ensure the periodic re-assessment and monitoring of medicines, complementary medicines, veterinary medicines and devices;

(d) ensure that evidence of existing and new adverse events, interactions, information about pharmaco-vigilance is being monitored globally, analysed and acted upon;

(e) ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation; and

(f) ensure that clinical trial protocols are being assessed according to prescribed ethical and professional criteria and defined standards.

Constitution of Board

6. (1) The Minister must within six months after the date of commencement of this Act, appoint a Board which consists of—

(a) a chairperson;

(b) a vice-chairperson;

(c) a person representing the Minister of Agriculture;

(d) a person representing the Minister; and

(e) no fewer than five, but not more than eleven other persons as the Minister may determine.

(2) The Board must, in consultation with the Minister, appoint an executive committee from among its members, which mus consist of the chairperson, vice-chairperson and no more than three other members, one of whom must be the Board member representing the Minister of Agriculture.

(3) The Minister must determine whether a personal pointed to the Board must serve in a full-time or part-time capacity.

(4) The Chief-Executive Officer and chairpersons of Standing Committees appointed by the Board are *ex officio*, non-voting members of the Board.

(5) All acts of the Board are regarded as the acts of the Authority.

Qualifications of members of Board

7. (1) Members of the Board must be appropriately qualified, fit and proper persons who—

(a) are committed to—

(i) the objects of this Act; and

(ii) fairness, openness and accountability or the part of those entrusted with providing the public with access to medicines, complementary medicines, veterinary medicines and devices and

(b) when viewed collectively represent a broad toss-section of the population of the Republic.

Disqualification of members of Board

8. (1) A person may not be appointed or continue i s a member of the Board if that person—

(a) is not a South African citizen;

(b) is not permanently resident in the Republic;

(c) is disqualified under the Veterinary and Para-Veterinary Professions Act, 1982 (Act No 19 of 1982), the Chiropractors, Homeopaths and Allied Health Service Professions Act, 1982 (Act No 63 of 1982), the Health Professions Act, 1974 (Act No 56 of 1974), or the Pharmacy Act, 1974 (Act No 53 of 1974), the Nursing Act, 1978 (Act No 50 of 978), or any other professional body, from carrying on that person's profession, while so disqualified;

(d) is employed by, or represents the interests of the medicines', complementary medicines', veterinary medicines' or devices' industry;

(e) is an elected member of Parliament, provincial legislature or local government:

(f) or an immediate family member of that persor has a controlling interest or any substantial financial interest in the medicines', complementary medicines', veterinary medicines' and medical devices' industry;

(g) or the business partner of that person holds an office in or with or is employed by any person, company, organisation or other body, whether corporate or unincorporated, which has an interest contemplated in paragraph *(f)*;

(h) is an unrehabilitated insolvent;

(i) is declared by a court of competent jurisdiction as being mentally ill, as defined in the Mental Health Act, 1973 (Act No 18 of 1973);

(j) has at any time been convicted, whether in the Republic or elsewhere, of—

(i) theft, fraud, forgery or uttering a forged document, perjury, an offence in terms of the Corruption Act, 1992 (Act No 94 of 1992), or any other offence involving dishonesty;

(ii) any offence corresponding materially to any offence referred to in subparagraph *(i)*.

(2) A person who was subject to a disqualification contemplated in subsection (1)*(a)* to *(i)* may be appointed as a member of the Board if at the time of such appointment that person is no longer subject to that disqualification.

Term of office of members of Board

9. (1) A member of the Board holds office for a term not exceeding five years, and may be re-appointed once for another term of office no exceeding five years.

(2) A member of the Board may at any time, on at least three months' written notice addressed to the Minister or such shorter notice period as the Minister may authorise, resign from the Board.

(3) Despite subsection (1), a member of the Board may, with the authority of the Minister, remain in office after completion of that member's term of office until commencement of the term of office of that member's successor but such increased term of office must not exceed 45 days.

(4) A member of the Board who has been appointed o serve in a full-time capacity, serves in such capacity to the exclusion of any other remunerative employment, occupation or office.

(5) Despite subsection (4), the Minister may, on such terms and conditions as the Minister may determine, permit a member appointed to serve in a full-time capacity to hold other remunerative employment, occupation or office.

Removal from office

10. Despite section 9, a member of the Board may be removed from office by the Minister on account of—

(a) misconduct, which may include violating the Code of Conduct determined by the Board and published by notice in the *Gazette*;

(b) inability to perform the duties of that member's office effectively;

(c) absence from three consecutive meetings of the Board without the prior permission of the chairperson, except on good cause shown;

(d) having performed other remunerative work in contravention of section 9(4); or

(e) failure to disclose an interest in terms of section 14(3)(u) or attendance at or participation in proceedings of the Board while having an interest contemplated in section 14(1) and (2).

Vacancies in Board

11. (1) A member of the Board vacates office if that member—

(a) becomes subject to a disqualification referred to in section 8;

(b) tenders resignation as contemplated in section 9(2) and such resignation takes effect;

(c) is removed from office in terms of section 10; or

(d) becomes permanently incapacitated.

(2) If the office of any member becomes vacant before the expiration of the period for which that member was appointed, the Minister must, subject to sections 6 and 7 appoint another person to hold office for the unexpired portion of the period for which that person's predecessor was appointed.

Meetings of Board

12. (1) The Board must meet at least eight times a year, and meetings must be held at such times and places as the Board may determine, but the first meeting is held at such time and place determined by the chairperson after consultation with the Minister.

(2) In the absence of the chairperson, the vice-chairperson will perform all the functions of the chairperson, and in the absence of both the chairperson and the vice-chairperson, the other members of the Board must from their number elect an acting chairperson.

(3) The chairperson may at any time, convene a special meeting of the Board, which must be held at such time and place as the chair-person may determine but the chairperson must, upon the request of the Minister or upon being presented with a requisition for that purpose signed by at least three members of the Board, convene a special meeting, and if the chairperson fails to convene a special meeting within seven days of receipt of the Minister's request or the presentation of the requisition by three members of the Board, the members of the Board may convene a special meeting.

(4) The quorum for any meeting of the Board is the majority of the voting members.

(5) Subject to subsection (4), a decision of the Board must be taken by resolution agreed to by the majority of the members of the Board at any meeting of the Board and, in the event of an equality of votes regarding any matter, the chairperson has a casting vote in addition to the chairperson's deliberative vote.

(6) The Executive Committee may, subject to the direction of the Board, exercise all the powers and perform all the functions of the Board during periods between meetings of the Board, but must not have the power, save in so far as the Board directs, to set aside or vary any decision of the Board, and any action taken or decision made by the Executive Committee must be subject to ratification at the first ensuing meeting of the Board.

Remuneration and allowances of members of Board

13. The chairperson and other members of the Board other than persons who are in the full-time employment of the State are paid such remuneration and allowances and are entitled to such benefits as the Minister may, after consultation with the Board and with the concurrence of the Minister of Finance, determine

Disclosure of conflicting interests

14. (1) A member of the Board or of the staff or of any committee of the Authority, may not vote at, attend or in any other manner participate in the proceedings of any meeting or hearing of the Board or any committee of the Authority if—

(a) in relation to an application for the registration of a medicine, complementary medicine, veterinary medicine, clinical trial or device, that member or that member's immediate family member or business partner is a director, member or business partner of or has an interest in the business of the applicant or of any person who made representations in relation to the application; or

(b) in relation to any matter before the Authority, has any interest which precludes or may be perceived as to preclude that member from performing that member's functions as a member of the Authority in a fair, unbiased and proper manner.

(2) For the purpose of this section, "interest" includes, but is not limited to, any consultancy, paid or unpaid, any research grant from which the member directly or indirectly benefits, or any equity holding or any executive or non-executive directorship or any other payment or benefit in kind.

(3) If at any stage during the course of any proceedings of the Board or committee of the Authority there is reason to believe that a member of the Board or committee of the Authority has an interest contemplated in subsection ( ), that member—

(a) must forthwith and fully disclose the nature of that member's interest and leave the meeting or hearing in question so as to enable the remaining members of the Board or any committee of the Authority to discuss the matter and determine whether that member should be precluded from participating in such proceedings by reason of a conflict of interests; and

(b) such disclosure and the decision taken by the remaining members of the Board or any committee of the Authority regarding such determination, must be recorded in the minutes of the proceedings in question.

Proceedings of Authority not invalid in certain circumstances

15. A decision taken by the Authority, or an act performed under the authority of such decision is not invalid merely by reason of—

(a) any irregularity in the appointment of a member of the Board;

(b) the fact that a member of the Board is guilty of an act justifying that member's removal from office; or

(c) the fact that any person who is disqualified from being a member of the Board or who was removed from that office sat as such in the Board at the time when such decision was taken,

if such decision was taken by a majority of the members of the Board lawfully entitled to vote and present at the time, and the said members of the Board at the time constituted a quorum.

Staff of Authority

16. (1) The Authority must, in consultation with the Public Service Commission and subject to the approval of the Minister with regard to staff and resources, establish its own administration to perform its functions.

(2) The Board must in consultation with the Minister, on such terms and conditions as may be determined, appoint a Chief Executive Officer who is the secretary of the Board and who-

(i) must receive such remuneration, allowances and other benefits as the Board may determine in consultation with the Minister with the concurrence of the Minister of Finance;

(ii) must, on such terms and conditions as may be determined by the Board after consultation with the Public Service Commission and subject to the approval of the Director-General with regard to resources, appoint such staff as may be reasonably necessary to: assist the Chief Executive Officer with the work incidental to the performance by the Authority of its functions;

(iii) must, subject to this Act, be responsible for the management of and administrative control of the staff of the Authority and must for those purposes be accountable to the Board; and

(iv) may exercise the powers and must perform the duties and functions which the Board may from time to time confer upon or assign to the Chief Executive Officer in order to achieve the objects of the Authority, and must for those purposes be accountable to the Board.

(3) The Authority must, in the appointment of its staff—

(a) provide for the advancement of persons disadvantaged by past unfair discrimination, with the aim that its staff, when viewed collectively, must represent a broad cross-section of the population of the Republic, and;

(b) subject to paragraph *(a)* apply equal opportunity employment practices.

(4) The Authority may pay to the persons in its employ such remuneration and allowances and provide them with such pensions and other benefits as the Board may determine in consultation with the Minister and with the concurrence of the Minister of Finance and after consultation with the Public Service Commission.

(5) Any officer or employee of the Department may be selected by the Authority, in consultation with tbe Director-General, for transfer to the Authority, and if so selected must, despite any provision to the contrary in the Public Service Act, 1994 (Proclamation No 103 of' 1994), but subject to the Labour Relations Act, 1995 (Act No 66 of 1995), as from the fixed date or such later date as may be agreed upon between the Director-General and the Authority. cease to be such officer or employee and, without interruption of service become an employee of the Authority.

(6) Any person so transferred must, with effect from the date of that person's transfer, be appointed by the Authority on the conditions determined by it to an appropriate post in the Authority but that—

(a) such person's salary or salary scale must not be reduced by such appointment;

(b) such person must retain all vacation and sick leave standing to that person's credit with the Department immediately preceding that person's transfer, including all monetary benefits attached thereto;

(c) such person must be, compensated for any loss which that person may incur as a result of such transfer in respect of unemployment contributions, medical aid contributions or other expenditure on health care that is necessary so as not to place that person in a less favourable position with regard to such than that which applied to him or her immediately prior to that person's transfer, as well as for any other loss arising from any transfer from that person's present headquarters to new headquarters in accordance with the procedure applicable to officers and employees of the Department; and

(d) such person's conditions of employment in respect of matters not specified in paragraphs *(a)* to *(c)* of this subsection must not be less favorable to that person than those which applied to that person prior to the transfer.

(7) Any person transferred from the Department in terms of subsection (5) who immediately prior to such transfer was a member of the Government Employees Pension Fund, must despite any provision to the contrary in any law or in the rules of that pension fund, upon transfer remain a member of that pension fund for all purposes and the Authority must contribute to the said pension fund in respect of that person to the same extent as an employer is required in terms of the laws on, and the rules of, that pension fund to contribute to that pension fund in respect of an employee who is a member of that fund.

(8) For the purposes of the Income Tax Act, 1962 (Act No S8 of 1962), no change of employer is deemed to have taken place when an officer or employee of the Department is transferred to the Authority in terms of subsection (5), and the position of such officer

or employee in respect of the phasing in of tax levied on a benefit or advantage derived by reason of employment or the holding of any office as contemplated in Schedule 7 to the Income Tax Act, 1962, must be deemed to remain unchanged.

(9) Any disciplinary steps instituted or contemplated against any person transferred from the Department in terms of subsection (5) in respect of alleged misconduct committed prior to that person's transfer to the Authority, must be disposed of or instituted, as the case may be, in terms of the laws applicable to that person immediately before such transfer.

(10) At least one month before the fixed date, the Director-General must in writing inform every officer and employee of the Department who has been selected for transfer—

(a) that that person has been selected for transfer to the Authority in terms of subsection (5), and of the post that will be occupied by that person and the date on which transfer is to take effect and that such transfer will only be effected if that person consents to it; or

(b) in the event of that person refusing to consent to such transfer and after considering that person's representations—

(i) that that person's services are to be terminated, as from a specified date, owing to the abolition of that person's post in the Department; or

(ii) that in terms of section 14 of the Public Service Act, 1994, that person must be transferred from the post or position occupied by that person to any other post or position in that person's Department, irrespective of whether such a post or position is in another division, or is of a lower or higher grade, or is within or outside the Republic,

(11) Any proposed action of which an officer or employee is notified in terms of subsection (10) may be a subject of an appeal to the Minister.

(12) Any such appeal must be lodged within 14 days of receipt of such notification by the officer or employee.

(13) Any person contemplated in subsection (10)*(b)* is entitled to special severance conditions and benefits not less favourable to that person than those prescribed under the Public Service Act, 1994, in respect of a person to whom that Act applies and whose services are terminated because of the abolition of that person's post.

(14) For the purpose of this section "fixed date" means the date determined by the Minister by notice in the *Gazette*.

Financing of Authority

17. (1) The operating and capital costs of the Authority are financed from monies appropriated by Parliament from time to time.

(2) Despite subsection (1) the funds of the Authority may consist of—

(a) such fees or charges for services rendered as may be prescribed;

(b) monies raised, borrowed or obtained by the Authority in terms of section 18;

(c) monies obtained from any other source.

(3) The Authority may in the prescribed manner receive donations or contributions from any person, and must use any donation or contributions so acquired for such purposes as it may determine in connection with the performance of its functions in terms of this Act: provided that all such contributions are published in the annual report of the Authority.

(4) The Authority may utilise any balance of its monies remaining at the end of any financial year of the Authority for any expenses in connection with the performance of its functions in terms of this Act.

(5) The funds contemplated in subsection (2) do not form part of the National Revenue Fund.

Loans

18. (1) The Authority may, with the approval of the Minister granted after consultation with the Minister of Finance, raise money with or borrow or obtain money from any person or body at such rate of interest and on such conditions as the Minister may determine.

(2) Subject to section 35 of the Exchequer Act, 1975 (Act No 66 of 1975), the Minister may, with the concurrence of the Minister of Finance, for the period and on the conditions which the Minister may determine, guarantee due performance by the Authority of any contractual obligation incurred or o be incurred by the Authority towards any party whether within or outside the Republic.

Finances of Authority

19. (1) The Authority must, except in so far as 'his Act may otherwise provide, utilise its assets for the attainment of its objects and n atters incidental thereto.

(2) The Authority may establish a reserve fund for: uch purposes as, with due regard to subsection (l). it may deem fit and must with the ap,roval of the Minister of Finance invest in any manner to the advantage of the Authority that portion of the monies in the reserve fund which it does not require immediately.

(3) The Board must cause proper records to be kep' of all the financial transactions, assets and liabilities of the Authority and must for tha. purpose, and after consultation with the Minister, appoint an audit committee which rm st consist of the Auditor-General or the Auditor-General's representative and at least or e member of the Board.

(4) The accounts of the Authority must be audited a nually by a person registered as an auditor under the Public Accountants and Auditors' Act, 1951 (Act No. 80 of 195 l), and who must be appointed by the Board in consultatic n with the Minister and with the concurrence of the Auditor-General.

(5) As soon as may be practicable after the complet on of every audit the Board must furnish the Minister and the Auditor-General with a anr ual report of the audit containing such particulars as may be prescribed, together with a report on the activities of the Authority containing the prescribed particulars, and d e Minister must table a copy of the annual report in Parliament within 30 days of receiv ing it if Parliament is in ordinary session, but if Parliament is not in ordinary session, within 30 days after the commencement of the next ensuing ordinary session.

(6) The Board must furnish the Minister with such nformation as the Minister may call for from time to time require in respect of the acti ities or financial position of the Authority.

Banking account

20. The Board must open and maintain in the nan e of the Authority with a bank registered as a bank in terms of the Banks Act, 1990 (Act No 94 of 1990). an account in which there must be deposited the moneys received b y the Authority and from which payments by the Authority or on its behalf must be m: de.

CHAPTER III

COMMITTEES AND APPOINTMENT OF EXPERTS

Establishment of committees of Authority

21. (1) The Board must, in consultation with t ne Minister, establish standing committees, and appoint their chairpersons and deputy chairpersons for, but not limited to—

(a) orthodox medicines, which must consist of experts from the relevant scientific disciplines;

(b) complementary medicines, which must consist of persons representing skills or experience in complementary medicines, oxicology and clinical pharmacology;

(c) veterinary medicines, which must consist of species specialists and experts from the relevant scientific disciplines; and

(d) medical devices, which must consist of persons with the specialist expertise required in this area of public health regulation.

(2) Subject to subsection(1). the Board may establish such other committees for such

purposes as it may deem necessary in order to assist it in the effective performance of its functions and may at any time extend, limit or dissolve any such committee.

(3) The Chief' Executive officer must appoint a secretariat which must provide administrative assistance to the committees of the Aut ıority.

(4) The Board may appoint any appropriately quali ied person who is fit and proper to the committees established in terms of this section.

Remuneration and allowances of committee members

22. (1) A member of any committee of the Board who is not a member of the Board or on the staff of the Authority or in the full-time employ of the State must be paid such remuneration and allowances as the Board may from time to time in consultation with the Minister and the concurrence of the Minister of Finance, determine.

(2) For the purposes of subsection(I), the Board may differentiate between different committees and different members thereof.

Appointment of experts

23. (1) The Authority may for the purposes of the performance of its functions, appoint experts, including experts from other countries.

(2) The terms, conditions, remuneration and allowances applicable in respect of any expert by virtue of that expert's appointment, must be determined in a written agreement entered into for that purpose between the Authority and the expert concerned.

CHAPTER IV

Registration of medicines, complementary medicines, veterinary medicines and medical devices

24. (I) An application for the registration of a med tine, complementary medicine, veterinary medicine or device must be submitted to the Authority in the prescribed form and must be accompanied by the prescribed particulars and samples, where appropriate, and by the prescribed fees.

(2) As soon as the Authority has received an application it must—

(a) acknowledge receipt of such application and, ensure that if such an application is in respect of a medicine or complementary medicine which appears on the essential drugs list or which does not appear thereon but which, in the opinion of the Minister, is essential for national health, is subject to such procedures as may be prescribed in order to expedite a decision thereon;

(b) after conducting an investigation or inquiry on such medicine, complementary medicine, veterinary medicine or device and i fit is satisfied that the medicine, complementary medicine, veterinary medi :ine or device in question is suitable for the purpose for which it is intended, complies with the prescribed requirements and that its registration is in the public interest, approve of its registration;

(c) if not satisfied that the medicine, complementary medicine, veterinary medicine or device in question is suitable 'or the purpose for which it is intended, complies with the prescribed requirements and that its registration is in the public interest. cause the applicant to be notified in writing of the reasons why it is not satisfied, and cause the applicant to be informed that it or the applicant may within a period of 60 days after the date of the notification, furnish the Authority with the applicant's comments on the Authority's reasons for not being satisfied;

(d) if the comments referred to in paragraph *(c)* are not submitted within the period of 60 days, or if after consideration of the comments submitted by the applicant it is still not satisfied, reject the application.

(3) For the purposes of this section, "essential drug list" means the list of essential drugs included in the latest edition of the official publication relating to guidelines for standard treatment which is compiled by the Department.

(4) For the purposes of the investigation or inquiry contemplated in subsection (2)*(b)*

the Authority may, determine different processes or guidelines for the evaluation of orthodox medicines, complementary medicines, veterinary medicines or devices or any class or category thereof.

(5) After the Authority has approved the registration of a medicine, complementary medicine, veterinary medicine or device, it must register it and must enter such particulars in regard to the medicine, complementary medicine, veterinary medicine or device as may be prescribed to be so entered in the register and must in regard to that medicine, complementary medicine, veterinary medicine or device, issue to the applicant a certificate of registration in the prescribed form.

(6) The Authority must as soon as possible after any orthodox medicine, complementary medicine, veterinary medicine or device has been registered notify anybody it considers necessary to be notified and, by notice in the *Gazette*, publish—

(a) the name and registration number of such orthodox medicine, complementary medicine, veterinary medicine, or device and the conditions, if any, to which the registration of such orthodox medicine, complementary medicine, veterinary medicine or device is subject;

(b) therapeutic efficacy of such orthodox medicine, complementary medicine, veterinary medicine or device;

(c) the pharmacological purpose or any other purpose for which, the circumstances under which and the manner in which such orthodox medicine, complementary medicine, veterinary medicine or device should be used; and

(d) regarding any other matter concerning such medicine, complementary medicine or veterinary medicine which, in he opinion of the Authority, may be of value to them.

(7) A medicine. complementary medicine, veterinary medicine or device which has been registered, including one registered prior to the commencement of this Act may, subject to subsection (10) be subject to re-registration by the Authority.

(8) A medicine. complementary medicine, veterinary medicine or device must be registered under such name as the Authority may approve, and the Authority must allocate to such registered medicine, a registration number which must be stated in certificate of registration issued in respect of such medicine, complementary medicine, veterinary medicine or device or any class or category thereof.

(9) Any registration under this section. including a re-registration in terms of subsection (7) must, in the public interest and so as to ensure the quality, safety, and efficacy of the medicine, complementary medicine, veterinary medicine or device and, in order to review reports of suspected adverse drug events, be valid for such period as may be determined by the Authority and may be subject to such conditions as the Authority may determine.

(10) No re-registration in terms of subsection (7) may be made, and no condition contemplated in subsection (9) may be determined, until after the bolder of a certificate of registration has been invited to make representation, as to why there should not be the re-registration contemplated in subsection (7), or the conditions contemplated in subsection (9) should not be determined and imposed by the Authority, or should not be in the terms contemplated by the Authority but if the holder of a certificate of registration has not made such representation within a period of one month after receipt by it or him or her of the Authority's invitation, or if after the consideration of any such representations, the Authority is still of the opinion that the medicine, complementary medicine, veterinary medicine or device should be de-registered or the condition it contemplates should be determined and imposed, it must de-register the medicine, complementary medicine, veterinary medicine or device and may thereafter, and subject to subsections (2) and (5), re-register it subject to any condition it contemplates.

(1 I) The Authority must in writing notify the holder of a certificate of registration of its decision to cancel a registration or to re-register subject to any condition, the orthodox medicine, complementary medicine, veterinary medicine, or device, and it must by notice in the *Gazette*, make known such decision but no such notification must be given if the holder of a certificate of registration had lodged an appeal in terms of

section 26 against such decision of the Authority but further, that if any appeal so lodged is dismissed, the Authority must as soon as possible after the decision dismissing the appeal has been given, proceed with the notification.

(12) The Authority may on application by the holder of a certificate of registration, and if there is good cause for doing so, and subject to such application being in the prescribed form and accompanied by the prescribed fee, amend an entry made in the register.

For the purpose of this subsection "good cause" may include the need to transfer the certificate of registration to another person.

(13) Despite subsection (9), the Authority may, after considering the representations of a holder of a certificate of registration cancel any registration in terms of this Act if it is of the opinion that—

(i) the holder of the certificate of registration or the agent of such holder has failed to comply with the condition to which the medicine, complementary medicine, veterinary medicine or device is subject: or

(ii) a medicine, complementary medicine, veterinary medicine or device no longer complies with a prescribed requirement; or

(iii) after an evaluation conducted on such orthodox medicine, complementary medicine, veterinary medicine or device, it is no longer in the public interest to have it available to the public.

(14) The Authority must in writing notify the holder of a certificate of registration, the Health Professions Council of South Africa, the South African Veterinary Council, South African Pharmacy Council, the Interim Co-ordinating Committee of Traditional Medical Practitioners of South Africa, the Nursing Council or its successor in title and, by notice in the *Gazette*, make known its decision to cancel the registration, and the grounds in terms of subsection (13) for such cancellation.

(15) The Authority's decision to cancel the registration is subject to an appeal in terms of section 26.

Prohibition on manufacture, packaging, distribution, marketing and sale of medicines, complementary medicines, veterinary medicines and devices which are subject to registration and are not registered

25. (I) Subject to the provisions of this section or sections 30, 31 and 32, it is an offence punishable with a fine or imprisonment not exceeding 10 years or both such fine and imprisonment, to manufacture, package, distribute, market or sell medicines, complementary medicines, veterinary medicines or devices which are subject to registration and which are not registered, or which do not comply with the prescribed requirements.

(2) Without derogating from the generality of sub: ection (I), the Authority may by resolution approved by the Minister, determine that an orthodox medicine, complementary medicine, veterinary medicine or device or class or category of an orthodox medicine, complementary medicine, veterinary medicine or device or part of any class or category of an orthodox medicine, complementary medicine, veterinary medicine or device mentioned in the resolution is subject to registration in terms of this Act.

(3) Any such resolution may also relate only to medicines, complementary medicines, veterinary medicines or devices which were available for sale in the Republic immediately prior to the date when it comes into operation in terms of subsection (4)or only to orthodox medicines, complementary medicines, veterinary medicines or devices which were not then so available.

(4) Any such resolution becomes effective when it is published in the *Gazette*.

(5) In the case of a medicine, complementary medicine veterinary medicine or device which was available for sale in the Republic immediately prior to the date of publication in the *Gazette* of the resolution by virtue of which it is subject to registration in terms of this Act, the provisions of subsection (1) come into operation—

(a) if no application for the registration of such orthodox medicine, complementary medicine, veterinary medicine, or device is made within the period of six months immediately succeeding that date, a the expiration of that period: or

(b) if application for the registration of such orthodox medicine, complementary

medicine, veterinary medicine, or device is made within the said period, on the date one month after the date on which notice regarding the rejection of the application for registration of such medicine, complementary medicine, veterinary medicine or device is published in the *Gazette*.

(6) Subsection (1) does not apply in respect of the sale of any medicine, complementary medicine or veterinary medicine—

(a) compounded in the course of carrying out of professional activities by a pharmacist, pharmacist intern, pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974 (Act No. 53 of 1974). veterinary: n or person who is a holder of a licence contemplated in section 33 for a particular patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or

(b) compounded by a pharmacist in a quantity not greater than that prescribed for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed, by a medical practitioner, or a dentist or a veterinarian or a practitioner or a nurse or other person registered under the Medical, Dental and Supplementary Health Professions Act, 1974 (No. 56 of 1974), and referred to in section 31, as the case may be, if such medicine 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 or has not been advertised but the active components of such orthodox medicine, complementary medicine or veterinary medicine appear in another orthodox medicine, complementary medicine or veterinary medicine which has been registered under this Act.

Appeal against decision of Authority

26. (1) The Minister must appoint an Appeal Board which must be impartial and independent of the Authority and which must consist of a maximum of five appropriately qualified persons who are fit and proper persons to be so appointed, but the chairperson thereof must be a person appointed on account of that person's knowledge of the law.

(2) The members of the Appeal Board who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister may with the concurrence of the Minister of Finance determine.

(3) Subject to subsection (4) the Appeal Board must hear and decide on all appeals by persons aggrieved by any decision of the Authority, including a decision not to register a medicine, a complementary medicine, a veterinary medicine, or a device, or to cancel any such registration.

(4) The Minister must by regulation determine the rules and procedures to be followed by the Appeal Board in hearing appeals, including the power to refuse to hear an appeal if it is of the opinion that the appellant is vexatious or there is no genuine ground for appeal, and the number of the members of the Appeal Board which may hear an appeal.

Furnishing of information regarding orthodox medicines, complementary medicines, veterinary medicines or devices to Authority

27. The Authority may by notice in writing require any person who manufactures or sells or administers, prescribes or dispenses any orthodox medicine, complementary medicine, veterinary medicine, device or on whose direction any orthodox medicine, complementary medicine, veterinary medicine, or device is manufactured or sold or administered or prescribed to furnish it within a period stipulated in such notice, with any information which such person has in his or her or possession or which such person is in a position to obtain regarding such orthodox medicine, complementary medicine, veterinary medicine or device but the Authority may, if so requested by any person to whom such notice is addressed, extend the period stipulated in such notice.

CHAPTER V

MEASURES TO CONTROL LABELS AND ADVERTISING, SALE OF UNREGISTERED MEDICINES, COMPLEMENTARY MEDICINES, VETERINARY MEDICINES AND DEVICES AND CONTROL OF MEDICINES, COMPLEMENTARY MEDICINES, VETERINARY MEDICINES AND DEVICES

Labels and advertisements

28. (I) No person may sell any orthodox med'tine, complementary medicine, veterinary medicine, medical device, or Scheduled substance unless the immediate container of the package in which that orthodox medicine, complementary medicine, veterinary medicine, device or Scheduled substance is sold, bears a label stating the prescribed particulars.

(2) No person may advertise any orthodox medicine, complementary medicine, veterinary medicine, device or Scheduled substance for sale unless such advertisement complies with the prescribed requirements.

(3) The Authority must approve the label contemplated in subsection(1).

(4) The Authority may authorise a deviation from the prescribed format and contents of any label.

(5) The Minister may, in consultation with the Authority, prescribe additional requirements for the labelling of medicines.

Publication or distribution of false advertisement concerning orthodox medicines, complementary medicines, veterinary medicines, or devices

29. (l) No person may—

(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 orthodox medicine, complementary medicine, veterinary medicine or device, whether registered or not; or

(b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any orthodox medicine, complementary medicine, veterinary medicine, or device is other than stated by he Authority in terms of section 24(6)(b) or state or suggest that any orthodox medicine, complementary medicine, veterinary medicine, or device should be used for a purpose or under circumstances or in a manner other than that stated by the Authority in terms of section 24(6)(c).

(2) It is a sufficient defence in any prosecution for an offence under subsection (l)*(a)* if it is proved to the satisfaction of the court that the accused, not being a person selling the orthodox medicine, complementary medicine, veterinary medicine, or device 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 Authority or an inspector or a member of the South African Police Service 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.

Authorisation by Authority of sale of unregistered orthodox medicine, complementary medicine, veterinary medicine, or device for certain purposes

30. (l) The Authority may in writing authorise any person to sell during a specified period to any specified person or institution a specified quantity of any particular orthodox medicine, complementary medicine, veterinary medicine or device which is not registered.

(2) Any orthodox medicine, complementary medicine, veterinary medicine, or device sold pursuant to any authorisation under subsection (1) may only be used for such purposes and in such manner and during such period as the Authority may in writing determine.

(3) The Authority may at any time by notice in writing withdraw any authorisation granted in terms of subsection (1) if effect is not g ven to any determination made in terms of' subsection (2).

Control of orthodox medicines, complementary nedicines, veterinary medicines, devices, and Scheduled substances

31. (1) Subject to this section, no person may, se 11, have in his or her possession or manufacture any orthodox medicine. complementary medicine, veterinary medicine, device, or Scheduled substance, except in accordance with the prescribed conditions.

(2) The Minister may on the recommendation of the Authority—

(a) prescribe the Scheduled substances referre d to in this section; and

(b) prescribe such Schedules as the Minister teems necessary.

(3) Any Schedule O substance may be sold in an open shop.

(4) Any Schedule 1 substance must not be sold—

(a) by any person other than—

(i) a pharmacist, pharmacist intern, or pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974;

(ii) a manufacturer of or wholesale deal er in pharmaceutical products for sale to any person who may lawfully possess such substance;

(iii) a medical practitioner or dentist, who may—

(aa) prescribe such substance; and

(bb) compound and dispense such substance only if that person is the holder of a licence as contempla ed in section 33;

(iv) a veterinarian who may prescribe, com pound or dispense such substance;

(v) a practitioner, nurse or a person regis ered under the Health Professions Act, 1974, other than a medical pract tioner or dentist, who may—

(aa) prescribe only the Scheduled sul stances identified in the Schedule for that purpose; and

(bb) compound and dispense the Scheduled substances referred to in item *(aa)* only if that person is the holder of a licence contemplated in section 33;

(b) to any person apparently under the age of 1$ years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacy support personnel in ac ordance with the scope of practice of such personnel as prescribed under tl e Pharmacy Act, 1974, or by a veterinarian or a person who is the holde of a licence as contemplated in section 33, or on a written order disclos ing the purpose for which such substance is to be used and bears a sign ature known to the seller as the signature of a person known to such seller a nd who is apparently over the age of 14 years;

(c) unless the seller, other than a manufacturer or wholesale dealer in pharmaceutical products, enters in a prescription book required to be kept in the prescribed manner, the prescribed particulars of such sale.

(5) Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance may not be sold by any person other than—

(a) a pharmacist, a pharmacist intern or pharmacy support personnel in accordance with the scope of practice of su ch personnel as prescribed under the Pharmacy Act. 1974, who may sell only Schedule 2 substances without a prescription;

(b) a pharmacist or a pharmacist intern or pharmacy support personnel in accordance with the scope of practice of su ch personnel as prescribed under the Pharmacy Act, 1974, who may sell only Schedule 2 substances without a prescription, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;

(c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;

(d) a medical practitioner or dentist, who may —
(i) prescribe such substance; or
(ii) compound or dispense such substance only if that medical practitioner or dentist is the holder 01 a licence as contemplated in section 33;
(e) a veterinarian who may prescribe, compound or dispense such substance;
(f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may-
(i) prescribe only the Scheduled substances identified in the Schedule for that purpose; and
(ii) compound and dispense the Scheduled substances referred to in subparagraph *(i)* only if he or she is the holder of a licence contemplated in section 33.

(6) Any sale under subsection (5) must only take place on condition that—
(a) all the prescribed particulars of every sale nust be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner;
(b) the authorised prescriber who has given verbal instructions to a pharmacist to dispense a prescription must within seven lays after giving such instructions, furnish such pharmacist with a prescription confirming such instructions;
(c) in the case of verbal instructions the treatment period must not exceed seven days;
(d) if a prescription is not presented for dispensing within 30 days of issue it must not he dispensed:
(e) in the case of a Schedule 2 substance, suet substance may not be supplied to any person apparently under the age of 1. years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacy support personnel in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974, or by a veterinarian or a person who is the holder of a licence as contemplated in section 33, or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 14 years;
(f) in the case of a Schedule 2, Schedule 3, or Schedule 4 substance, such sale may be repeated if the person who issued the prescription has indicated thereon the number of times it may be dispensed, but not for longer than six months;
(g) in the case of a Schedule 5 substance, such sale must not be repeated for longer than six months, and then only if the authorised prescriber has indicated on the prescription the number of times and the intervals at which it may be dispensed;
(h) where a Schedule 5 Substance is used by a person for-
(i) its anxiolytic, anti-depressant or tranquillising properties it must not be prescribed for longer than six months unless the authorised prescriber has consulted a registered psychiatric , or, in the case of a psychiatrist, another psychiatrist before issuing a new prescriptions; or
(ii) its analgesic properties it must not be prescribed for longer than six months unless the authorised prescriber has consulted another medical practitioner, before issuing a new prescription;
(i) in the case of a Schedule 6 substance, it must not be repeated without a new prescription being issued:
(j) in an emergency in which the health or life of a patient is at stake, a pharmacist engaged in wholesale practice may, on receipt of a telephonic or telefax or other electronic request, supply a Schedule 6 substance to a pharmacist. medical practitioner. dentist, veterinarian, practitioner, nurse or other persons registered under the Medical, Dental and Supplementary Health Service Professions Act, 1974, without a written order but—
(i) it must be the responsibility of such pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person to ensure that such pharmacist receives a written order within seven days;

(ii) the Schedule 6 substance must be sup plied in the smallest unit sales pack available: and

(iii) a permanent record is made and kept of such a supply.

(k) in an emergency a pharmacist may se] any Schedule" 5 or Schedule 6 substance in any quantity not greater than hat required for continuous use for a period of 48 hours, on the verbal instructions of a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under Health Professions Act, 1974, who is known to such pharmacist, but the prescriber who has given such verbal instruction must within 72 hours after giving such instructions furnish to such pharmacist a written prescription confirming the instructions:

(l) in an emergency a pharmacist may sell a Schedule 2, Schedule 3 or Schedule 4 substance on a non-recurring basis for a period not exceeding 30 days in accordance with tbe original prescription in order to ensure that the therapy is not disrupted if he or she is satisfied that an authorised prescriber initiated the therapy, with the intention that the the 'spy be continued, and that the particulars of such sale are recorded in a prescription book or other prescribed permanent record;

(lll) a pharmacist may sell a greater or a lesser quantity of a Schedule 1, Schedule 2. Schedule 3 or Schedule 4 substance. than the quantity prescribed or ordered, according to the therapeutic pat}. in the original container of such substance as supplied to the pharmacist, but the quantities so sold must not exceed or be less than, 25 percent of the quantity specified in the prescription or order in question;

(11) any seller referred to in this subsection must retain the prescription or order concerned for a period of not less than five years as from the date of such sale;

(o) a Schedule 6 substance may only be sold f the course of treatment does not exceed 30 consecutive days;

(p) the sale of a Schedule 5 or Schedule 6 substance by a manufacturer or a wholesale dealer in pharmaceutical products must be recorded in a register which must be kept in the prescribed manner, and must be balanced so as to show clearly the quantity of every Schedule 5 or Schedule 6 substance remaining in stock as of the last day of March, June, September and December of each year, and such balancing must be completed within the 14 days following each of the said dates:

(q) a pharmacist must endorse on the prescription the date of sale and the quantity of the substance sold, and when it is repeated, the date of sale and the quantity of the said substance sold and the last seller must retain the prescription for a period of not less than five years as from the date of the last sale; or

(1') any Schedule 1, Schedule 2. Schedule 3 or Schedule 4 substance for the treatment of any animal may be supplied by any person practicing a para-veterinary profession within the meaning of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 1982), upon a written prescription issued by a veterinarian or on the verbal instructions of a veterinarian.

(7) *(a)* No person, other than a pharmacist, or a pharmacist intern or pharmacy support personnel, in accordance with the scope of practice of such personnel as prescribed under the Pharmacy Act, 1974, may sell or export a Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, unless a permit. issued in accordance with the prescribed conditions has, subject to paragraph *(b)*, being obtained from the Authority for such purpose.

(b) The Authority may revoke any permit referred to in paragraph *(a)* if the conditions. for which such permit was issued, are not complied with or if it is not in the public interest that the particular action be continued

(8) Subject to subsection (9), a Schedule 7 substance must not be acquired by any person other than the Director-General for the purpose of providing a medical practitioner or veterinarian therewith, on the prescribed conditions, for the treatment of

a particular patient of that medical practitioner or veterinarian upon such conditions as the Director-General, on the recommendation of the Authority, may determine.

(9) *(a)* No person may—

(i) acquire, use, possess, cultivate, manufacture, or supply any Schedule 7 substance, or manufacture any Schedule 6 substance unless that person has been issued with a permit by the Authority for such acquisition, use, possession, manufacture, or supply but the Authority may, subject to such conditions as it may determine, acquire or authorise the use of any Schedule 7 substance in order to provide a medical practitioner, analyst, researcher or veterinarian therewith on the prescribed conditions for the treatment or prevention of a medical condition in a particular patient, or the purposes of education, analysis or research;

(ii) manufacture, use or supply any Schedule 5 or Schedule 6 substance for other than medicinal purposes unless he or she has been issued by the Authority with a permit for such manufacture, use or supply upon the prescribed conditions.

(b) Despite paragraph *(a)*, the Authority may at any time revoke any permit issued in terms of that paragraph if any condition on which the permit was issued has not been complied with,

(c) A permit issued in terms of this subsection must be valid for a period of 12 calendar months after the date of issue thereof.

(10) Despite anything to the contrary contained in this section, no person may sell or administer any Scheduled substance or orthodox medicine, complementary medicine or veterinary medicine for other than medicinal purposes but the Minister may, subject to the conditions or requirements stated in such authority, authorise the administration outside any hospital of any Scheduled substance or medicine for the satisfaction or relief of a habit or craving to the person referred to in such authority.

(11) *(a)* No person may import or export any Schedule 6 or Schedule 7 substance or other substance or medicine prescribed for that purpose unless a permit has been issued to that person by the Authority in the prescribed manner and subject to the prescribed conditions.

(b) A permit referred to paragraph *(a)* may be issued for any purpose other than the satisfaction or relief of a habit or craving in respect of such substance or orthodox medicine.

(c) The issue of a permit referred to in paragraph *(a)* may be refused if—

(i) the Authority is not convinced that the applicant is capable of keeping or storing the substance or medicine in a satisfactory manner *in* order to prevent the loss thereof;

(ii) the use of such substance or orthodox medicine or veterinary medicine has not been authorised in terms of this Act;

(iii) the Authority is of the opinion that the annual importation quota for such substance has been exceeded or will be exceeded;

(iv) the Authority is of the opinion that such substance or orthodox medicine or veterinary medicine of an acceptable quality, is already available in the Republic; or

(v) the applicant did not comply with the conditions under which a previous permit was issued to that applicant.

(d) If an application is refused, the applicant must be furnished with the reasons for such refusal.

(e) A permit issued in terms of this subsection is valid for a period of six months from the date of issue thereof.

(12) *(a)* The control on the importation of Scheduled substances must relate to—

(i) any Schedule 6 or Schedule 7 substance;

(ii) such substances irrespective of the scheduling status allocated thereto, as the Minister may prescribe;

(iii) any other substance which becomes subject to international control in terms of the 1961 Single Convention on Narcotic Drugs or 1971 Convention on Psychotropic Substances entered into by the Republic.

(b) The obtaining of import permits as required in terms of subsection (11) does not apply to any preparation which contains a substance as prescribed which is specifically exempted from all control measures for the obtaining of such import permit by the 1961 Single Convention on Narcotic Drugs referred to in paragraph *(a)*.

(c) Despite paragraph *(b)*, no such importation may take place unless authorised by the Authority.

(13) Any permit issued under subsection (11) must be subject—

(a) to the applicant's furnishing the Authority annually with the prescribed information;

(b) to the requirement that there must be no deviation from the particulars reflected on the permit but if the quantity of such substance or orthodox medicine or veterinary medicine to be imported, is less than that provided for in the permit, the Authority must be informed in writing thereof within 10 days after the importation of such substance or orthodox medicine, complementary medicine or veterinary medicine; and

(c) to the conditions, as detailed on the permit, having been complied with, and the triplicate copy of the permit having been certified by a customs officer or an employee of the S.A. Post Office Limited.

(14) Despite anything to the contrary contained in this section—

(a) a pharmacist's assistant may not handle any Schedule 6 substance except as contemplated in subsection (5)*(a)* and *(b, ;* and

(b) no nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe an orthodox medicine, or Scheduled substance unless that nurse or person has been authorised to do so within the scope of that nurse or person's practice by that nurse's or person's professional council concerned.

(15) Despite anything to the contrary contained in this section, the Authority may, after consultation with the Interim Pharmacy Council of South Africa or its successor in title as referred to in section 2 of the Pharmacy Act, 1974 (Act No. 53 of 1974), issue a permit to any person or organisation performing a health service, authorizing such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5: ubstance, and such permit must be subject to such conditions as the Authority may determine.

(16) Despite anything to the contrary contained in this section—

(a) any person may possess a Schedule O, Schedule 1 or Schedule 2 substance for medicinal purposes;

(b) any person may possess a Schedule 3, Schedule 4, Schedule 5, Schedule 6 or Schedule 7 substance if he or she has obtained a prescription issued by an authorised prescriber;

(c) any orthodox medicine, complementary medicine, veterinary medicine, or Scheduled substance may be possessed by a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, or under the Veterinary and Para-Veterinary Professions Act, 1982, for the purposes of administering it in accordance with that person's scope of practice;

(d) any medicine or Schedule substance may be possessed for sale by a pharmacist, a person licensed to own a pharmacy in terms of the Pharmacy Act, 1974, or a person who is the holder of a license as contemplated in section 33.

(17) For the purposes of this section—

(a) "authorised prescriber" means a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974; and

(b) "medicinal purpose" means for the purposes of the treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction or relief of a habit or craving for the substance used or for any other such substance, except where the substance is administered or used in a hospital or similar institution maintained wholly or partly by the Government or a provincial government or approved for such purpose by the Minister.

(18) *(a)* The Minister may, on the recommendation of the Authority, prescribe conditions for the manufacture, sale and possession of a medical device; and

(b) No person may manufacture, sell or have in his or her possession a medical device contemplated in paragraph *(a)* except in accordance with the prescribed conditions.

Exclusion of' orthodox medicine, complementary medicine or veterinary medicine or medical device from operation of Act

32. The Minister may, on the unanimous recommendation of the members present at any meeting of the Board, by notice in the *Gazette* exclude, subject to such conditions as the Minister may determine, any orthodox medicine, complementary medicine or veterinary medicine or medical device from the operation of any or all the provisions of this Act, and may in like manner amend or withdraw any such notice.

Licensing

33. (1) Subject to the provisions of this section—

(a) the Authority may, on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974 (Act No. 56 of 1974), a licence to dispense medicines, on the prescribed conditions;

(b) the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer importer, wholesaler or distributor of orthodox medicines, complementary medicines, veterinary medicines, or medical devices a licence to manufacture, import, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.

(2) A licence referred to in subsection (1)(a) must not be issued unless the applicant has successfully completed a supplementary course prescribed under the Pharmacy Act, 1974, by the South African Pharmacy Council.

(3) The Authority may require an applicant contemplated in subsection (1) to furnish such information, in addition to any information furnished by the applicant in terms of the said subsection, as the Authority may deem necessary.

(4) When the Authority grants or refuses an application for a licence—

(a) written notice must be given of that fact to the applicant; and

(b) in the event of the refusal of an application, the applicant must be furnished with the reasons for such refusal.

(5) No person may compound or dispense an orthodox medicine, complementary medicine or veterinary medicine unless that person is authorised thereto in terms of the Pharmacy Act, 1974, or is the holder of a licence as contemplated in subsection (1)*(a)*.

(6) No manufacturer, wholesaler, or distributor referred to in subsection (1)*(b)* may manufacture, act as a wholesaler of or distribute, as the case may be, any orthodox medicine, complementary medicine, veterinary medicine, or medical device unless that person is a holder of a license contemplated in the slid subsection.

(7) Subsections (5) and (6) come into operation six months after tbe commencement of this Act.

Period of validity and renewal of licence

34. A license issued under section 33 is valid for the prescribed period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Authority may allow and on payment of the prescribed fee.

Suspension and cancellation of licence

35. (1) If the holder of a licence under section 33—

(a) has in connection with an application for a licence or renewal of a licence furnished the Authority with any information which to the knowledge of such holder is untrue or misleading in any material respect;

(b) has contravened or failed to comply with a condition upon which the licence was issued;

(c) has contravened or failed to comply with a provision of this Act; or

(d) has, in the case of a licence issued in terms of subsection (1) of that section, at any time been convicted of an offence which is of such a nature that, in the opinion of the Authority, it renders that holder unsuitable to compound or dispense medicine,

the Authority may, by way of a notice in writing, call upon that person to show cause, within the period specified in the notice, which period must not be less than 20 days as from the date of the notice, why the licence in question should not be suspended or revoked.

(2) The Authority may after considering the reasons furnished in terms of subsection (1)—

(a) suspend the licence in question for such period as the Authority may determine; or

(b) revoke tbe licence in question.

(3) No person is entitled to the refund of any prescribed fee in respect of any application for the granting or renewal of a licence i" such application has been refused or if the licence has been suspended or revoked.

Disposal of undesirable orthodox medicines, complementary medicines, veterinary medicines and medical devices

36. (I) If the Authority is of the opinion that it is not in the public interest that any orthodox medicine, complementary medicine, veterinary medicine, or device be made 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 orthodox medicine, complementary medicine, veterinary medicine or device which that person has in possession to the manufacturer thereof, or (in the case of any imported orthodox medicine, complementary medicine, veterinary medicine, or device) to the importer concerned to deliver or send it to any other person designated by the Authority.

(2) The Authority may, by notice in writing direct any manufacturer or importer of any such orthodox medicine, complementary medicine, veterinary medicine or device who has in possession any quantity thereof (including any quantity returned, delivered or sent to that person in pursuance of a direction under subsection (1)), or any other person to whom any quantity of such orthodox medicine, complementary medicine, veterinary medicine or device has been so returned delivered or sent, to deal with or dispose of that quantity in such manner as the Authority may determine.

(3) No person may sell any orthodox medicine, complementary medicine, veterinary medicine or device, which is the subject of a notice under subsection (I) that has not been set aside on appeal.

Analysts, pharmacologists and pathologists

37. The Authority may grant such authority to such analysts, pharmacologists and pathologists as it may consider necessary for the proper enforcement of this Act.

Delegation of powers

38. The Board may in writing authorise the Chief Executive Officer or any officer of the Authority to exercise any of the powers conferrer I upon it by this Act other than the powers referred to in sections 6(2), 12, 16, 19, 21, 22, 28(4) and 30 in order to exercise or perform any of the duties or functions imposed on the Board in terms of this Act.

Commission or omission by manager, agent or employee

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

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

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

(c) it was not under any conditions 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 must be presumed to have done or omitted to do that act and must be liable to be convicted and sentenced in respect thereof; and the fact that the employer issued instructions forbidding any act or omission of the kind in question must not, of itself, be accepted as sufficient proof that the employer took a I 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 would be an offence under this Act for the employer to do or omit to do, that person may be liable to be convicted and sentenced in respect thereof as if that person were the employer.

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

CHAPTER VI

INSPECTORATE

Entry and search of premises

40. (1) The Authority must, for the proper enfo cement of this Act, designate such persons as it may deem necessary as inspectors.

(2) Any person designated as an inspector may, for the purposes of enforcing the provisions of this Act, and on the authority of a warrant issued in terms of subsection (6)—

(a) search any person suspected of having committed or committing any offence in terms of this Act; or

(b) enter upon and search—

(i) any place or premises from which a person authorised under this Act to compound and dispense medicines, complementary medicines, veterinary medicines or Scheduled substances or from which a holder of a certificate of registration as contemplated in section 24 conducts business, if it is suspected that an offence in terms of this Act is being committed; or

(ii) any place, premises, vehicle, vessel or aircraft, if the inspector has reason to suspect that an offence in terms of this Act, has been or is being committed at or in such place, premises, vehicle, vessel or aircraft or that an attempt has been made or is being made there to commit such an offence.

(3) The entry and search of any person, place, premises, vehicle, vessel or aircraft under this section must be conducted with strict regard to decency and order, including the protection of a person's right to—

(a) respect for that person's dignity:

(b) freedom and security; and

(c) that person's personal privacy.

(4) An inspector contemplated in subsection (1) may, subject to this section—

(a) inspect and search the person, place, premises, vehicle, vessel or aircraft in question, and there make such enquiries as the inspector may deem necessary;

(b) examine any medicine, complementary medicine, veterinary medicine, device, article or document found on de person, place, premises, vehicle, vessel or aircraft;

(c) request information regarding such medicine, complementary medicine. veterinary medicine, device article or document from the owner or person in control or agent of a person in control of the place, premises, vehicle, vessel or aircraft or from any person in whose possession or control that medicine, complementary medicine, veterinary medicine, device, article or document is, or who may reasonably be expected to have the necessary information;

(d) make copies of or take photographs or extracts from any document found on the person, place, premises. vehicle. vessel or aircraft:

(e) attach anything on or seize from the person, place, premises. vehicle, vessel or aircraft which has a bearing on the investigation;

(f) if the inspector wishes to retain anything contemplated in paragraph *(e)* for further examination or safe custody, remove it from the person, place, premises. vehicle, vessel or aircraft against the issue of a receipt but any medicine, complementary medicine, veterinary medicine. device, article or document that has been so removed, must be returned as soon as possible after the purpose for which it was removed has been achieved, but further that if there is no person present to receive the receipt when issued. it must be affixed to a prominent place of such place, premises, vehicle, vessel or aircraft.

(5) Any person from whom information is required in terms of subsection (4)*(a)* and *(c)* may be assisted in supplying the information b, a legal representative and must be so informed before being required to provide such information.

(6) *(a)* A warrant referred to in subsection (2) must only be issued in chambers by a magistrate or a judge of the High Court, if it appears to such magistrate or judge from information on oath that there are reasonable grounds for believing that any medicine, article or document which has a bearing on the investigation is in the possession or under the control of any person or on any place. premises, vehicle, vessel or aircraft situated within the area of jurisdiction of such magistrate or judge and cannot be reasonably obtained in any other manner.

(/?) A warrant referred to in subsection (2) must be executed by day unless the person who authorised it authorises the execution thereof at night, at times which are reasonable.

(c) A warrant referred to in subsection (2) may be issued on any day and must be of force until—

(i) it is executed: or

(ii) it is cancelled by the person who issued it: or, if such person is not available, by any person with like authority; or

(iii) the expiration of one month from the day of its issue,

whichever may occur first.

(d) A person executing a warrant under this section must at the commencement of such search, hand the person referred to in the warrant or the owner or the person in control or the agent of the person in control of the place, premises, vehicle, vessel or aircraft, if such person is present, a copy of the warrant, but if no such person is present, he or she must affix a copy of the warrant to the place, premises, vehicle, vessel or aircraft at a prominent and visible place.

(e) A person executing a warrant under this section must, at the commencement of such execution, identify himself or herself and if the owner or the person in control or the agent of the person in control of the place, premises, vehicle, vessel or aircraft requires authorisation to execute a warrant under this section, the particulars of such authorisation must also be furnished.

(7) *(a)* A person who may lawfully under this section enter and search any place, premises, vehicle, vessel or aircraft may use such force as may be necessary to overcome any resistance against such entry and search of the place, premises, vehicle, vessel or aircraft, including the breaking of any door or window of such place, premises, vehicle, vessel or aircraft.

(b) A person referred to in paragraph *(a)* must first audibly demand admission to the premises and notify the purpose for which that person seeks to enter such place, premises, vehicle, vessel or aircraft.

(c) Paragraph *(a)* does not apply where the person concerned is on reasonable grounds of the opinion that any medicine, complementary medicine, veterinary medicine, article or document which is the subject of the search may be destroyed, disposed of or tampered with if the provisions of paragraph *(b)* are complied with.

(8) If during the execution of a warrant in terms of subsection (6), a person claims that an article or document found on the person, place, premises, vehicle, vessel or aircraft contains privileged information and refuses the inspection of such article or document, the person executing the warrant may request the Registrar of the High Court which has jurisdiction or that Registrar's delegate, to attach and remove that article or document for safe custody until a court of competent jurisdiction has made a ruling on the question whether or not the information in question is privileged,

(9) If in the execution of a warrant in terms of subsection (6), it is necessary to use force to gain entry to a place, premises, vehicle, vessel or aircraft as contemplated in subsection (7)*(a)* and the force of such entry causes damage to any lock, door, window, wall or other part of such place, premises. vehicle, vessel or aircraft or to anything inside such place, premises. vehicle, vessel or aircraft, the Authority may request the Minister to authorise that such damage be made good from S, ate funds but no such request by the Authority and authorisation by the Minister must be made if the person responsible for the place, premises, vehicle, vessel or aircraft was present at the time of entry and failed, without just cause, to facilitate the entry.

(10) Subject to subsection (11), an inspector may, during the day, without a warrant enter upon and search any place, premises, vehicle, vessel or aircraft after having identified himself or herself, exercise the powers contemplated in paragraphs *(a)* and *(b)* of subsection (2), and subsection (4) (except the power to search any person), if—

(a) the person who is competent to consent to the entry and to such search; or

(b) the inspector on reasonable grounds believes that—

(i) the required warrant will be issued to him or her in terms of this section if he or she were to apply for the warrant; and

(ii) the delay that would ensue by first obtaining the warrant would defeat the object or purpose of the powers contemplated in paragraphs *(a)* and *(b)* of subsection (2) or subsection (4).

(II) Subsection 10*(b)* does not serve as authority for, and may not be applied for the purposes of, entering and searching a private dwelling.

(12) No answer given or statement made by any person to an inspector exercising the powers of the inspector in terms of paragraph *(a)* and (c) of subsection (4) or given or made to any inspector exercising like powers by virtue of subsection (10), will, if self incriminating, be admissible as evidence against that person in criminal proceedings instituted in any court against him or her.

(13) The provisions of subsection (3) regarding the manner in which a search must be conducted, and subsections (7)*(a)* and *(b)*, (8) and (9), will apply *mutatis mutandis* to an inspector acting by virtue of subsection (10).

(14) Despite subsection (2) an inspector may without a warrant during business hours conduct routine inspections of any place or premises from which a person authorised under this Act to manufacture, compound, dispense, distribute, advertise, or sell, any orthodox medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance, conducts business, in order to ensure compliance with any prescribed requirements.

Offences

41. Any person who—

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

(b) contravenes or fails to comply with the provisions of section 28 or section 33(1): or

(c) contravenes the provisions of section 27 or fails to comply with a notice issued under that section: or

(d) contravenes section 29(1); or

(e) contravenes or fails to comply with any condition imposed under section 24(6); or

(f) fails to comply with any direction given under section 36 or contravenes subsection (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 medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance—

(i) in an application for the registration, thereof; or

(ii) in the course of the sale thereof; or

(i) sells any medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance upon the container of which a false or misleading statement in connection with the contents is written; or

(j) for purposes of a business or trade makes use of any report or certificate made or issued by an inspector, analyst, pharmacologist or pathologist under this Act; or

(k) contravenes section 31 or contravenes or fails to comply with any condition imposed thereunder;

(l) contravenes or fails to comply with section 45,

is guilty of an offence.

Penalties

42. (1) Any person who is convicted of an offence referred to in section 41 is liable to a fine, or to imprisonment for a period not exceeding 10 years.

(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance in respect of which the offence has been committed to be forfeited to the state.

(3) Any medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance forfeited under this Act must be destroyed or otherwise dealt with as the Authority may direct.

(4) Despite anything to the contrary in any law contained, a magistrate's court is competent to impose any penalty provided for in this Act.

Presumptions and evidence

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

(a) any quantity of a medicine, complementary medicine, veterinary medicine or Scheduled substance 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 must, unless the contrary is proved, be deemed to possess the same properties as such sample;

(b) a certificate stating the result of a test, examination or analysis carried out in terms of the provisions of section 40 and purporting to be signed by the analyst, pharmacologist or pathologist who carried out such test, examination or analysis, may be accepted as *prima facie* proof of the facts stated therein;

(c) any statement or entry contained in any book, record or document kept by any owner of a medicine, complementary medicine, veterinary medicine, medical device or Scheduled substance, 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, must be admissible in evidence against that person 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 or her work as manager, or in the course of his agency or employment.

(2) 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 that person for reply, and such interrogatories and any reply thereto, purporting to be a reply from such person, is admissible in evidence in such proceedings,

CHAPTER VI1

WINDING UP OF AUTHORITY, PROHIBITION OF DISCLOSURE OF CERTAIN INFORMATION, REGULATIONS , REPEAL AND AMENDMENT OF CERTAIN SECTIONS OF ACT 101 OF 1965, ACT 36 OF 1947 AND SAVINGS

Winding up of Authority

44. The Authority may not be wound up excep by or under authority of an Act of Parliament.

Prohibition of disclosure of certain information

45. (1) No person who is a member of the Board, the staff of the Authority, committees of the Authority or providing any service to the Authority may, save as required by an order issued by a court of competen jurisdiction, disclose to any person any information in relation to the acquisition, supply, marketing, importation, export, development, manufacture, or research in tonnection with any orthodox medicine, complementary medicine, veterinary medicine or medical device preparation and or any other matter related thereto, by any applicant.

(2) Subsection (1) does not prohibit the disclosure of information—

(a) of decisions of the Board in accordance with its rules;

(b) where the Board considers the release would be in the interest of public health;

(c) by any member of the Authority in accordance with the provisions of the national legislation contemplated in sect on 3 1(2) of the Constitution; or

(d) released for publication by the Minister or by a person authorised thereto by the Minister in the interest of public health; or

(e) to other agencies nationally or internatior ally, if that is in accordance with the objects of the Authority and is necessary for the performance of the functions of the Authority.

(3) Any person who contravenes subsection (1), is guilty of an offence and liable on conviction to a fine, or to imprisonment for a perioc not exceeding 12 months or to both such fine and such imprisonment.

Proceedings by Minister in case of non-compliance with Act by Authority

46. (1) If at any time it appears to the Minister that the Authority has failed to comply with any of the requirements of this Act, the Minister may by notice in writing require the Authority to remedy the default within a specified time.

(2) If the Authority fails to comply with the terms of such notice, the Minister may apply to a court of competent jurisdiction for an order compelling the Authority to remedy the default, and the court may make such order thereon as it thinks tit.

Limitation of liability

47. No legal proceedings lie against any member of the Authority, its committees, or any person co-opted to any of its committees, or any person contracted by the Authority to assist it in the performance of its functions in terms of this Act, in respect of any act performed in good faith by any member of the Authority, its committees, or any person

co-opted to any of such committees, or any person contracted by the Authority to assist in the performance of its functions in terms of this Act.

Regulations

48. (1) The Minister may, in consultation with the Authority, make regulations—

(a) regarding the categories of persons by whom application may be made for the registration of any orthodox medicine, complementary medicine, veterinary medicine or device or to whom a certificate of registration may be transferred;

(b) regarding the format and forms which must be used for any application for the registration of any medicine and the particulars that must be furnished with any such application (including particulars regarding the method by which the orthodox medicine, complementary medicine or veterinary medicine in question or any component of such orthodox medicine, complementary medicine or veterinary medicine is manufactured and the premises at which such orthodox medicine, complementary medicine or veterinary medicine or any such component is manufactured);

(c) providing for the classification of orthodox medicines, complementary medicines, medical devices or veterinary medicines into classes or categories for the purposes of this Act;

(d) regarding the samples of any orthodox medicine, complementary medicine or veterinary medicine and the quantity thereof which must accompany any application for the registration of such orthodox medicine, complementary medicine, medical devices or veterinary medicine;

(e) regarding the form in which the register referred to in section 24(5) must be kept and the particulars which must be entered therein in respect of any registered orthodox medicine, complementary medicine, medical devices or veterinary medicine;

(f) regarding the form of any certificate of registration of any orthodox medicine, complementary medicine or veterinary medicine;

(g) regarding the circumstances in which, the conditions on which and the person or categories of persons to whom any orthodox medicine, complementary medicine, medical devices, veterinary medicine or Scheduled substance may be sold;

(h) regarding the manner in which any package containing any orthodox medicine, complementary medicine, medical devices, veterinary medicine or Scheduled substance must be labelled, packed or sealed;

(i) regarding the particulars in regard to the use thereof which must be furnished of any orthodox medicine, complementary medicine, veterinary medicine, medical devices or Scheduled substance sold which must be furnished, and the manner in which such particulars must be furnished;

(j) regarding the particulars which must appear in any advertisement relating to any orthodox medicine, complementary medicine, veterinary medicine or Scheduled substance, or prohibiting the inclusion of any specified particulars in such advertisement, or the distribution of any such advertisement to a specified person or a specified category of persons or to a specified organisation or a specified category of organisations;

(k) regarding the requirements with which any orthodox medicine, complementary medicine, medical devices or veterinary medicine, or any component thereof must comply in regard to composition, therapeutic suitability and effect, purity or any other property;

(l) regarding the particulars which must be published in the *Gazette* in respect of any application for registration referred to in section 24(I);

(m) regarding the particulars which must appear on a prescription or on an order for an orthodox medicine, complementary medicine, veterinary medicine or Scheduled substance, the number of issues of an orthodox medicine, complementary medicine, veterinary medicine or a Scheduled substance that may be made on any such specified prescription or order, the manner in which any such prescription or order must be issued and the period for which any such prescription or order must be retained;

(n) regarding the forms of licences, registers, prescription books, records and other documents which must be kept or used in respect of Scheduled

substances, the manner in which they must be kept, the particulars must be entered therein and the place where and the period for which they must be retained;

(o) requiring the furnishing of returns, reports and information in respect of Scheduled substances and plants from which any such substance can be extracted, derived, produced or manufactured, and in respect of any orthodox medicine, complementary medicine, veterinary medicine or other substance of which any such Scheduled substance is a component;

(p) regarding the transshipment or the exportation from or importation into the Republic of any Scheduled substance, specifying the ports or places at which such substance may be brought into the Republic;

(q) authorizing and regulating or restricting the transmission through the Republic of Scheduled substances;

(r) regarding the manner in which packages containing Scheduled substances must be labelled when imported into or manufactured in the Republic and the persons by whom and the manner in which they must be kept;

(s) authorizing and regulating the purchase, acquisition, keeping or use or preparation of cocaine by managers or persons in charge of factories, or workshops in connection with the treatment of eye injuries or for other essential purposes;

(t) authorizing and regulating the purchase, acquisition, keeping or use of Scheduled substances by particular persons or categories of persons;

(u) authorizing and regulating the possession by persons entering or departing from the Republic of specified quantities of Scheduled substances for personal medicinal use;

(v) as to the disposal or destruction of an orthodox medicine, complementary medicine, veterinary medicine or a Scheduled substance, and the records which must be kept in respect thereof;

(w) as to the importation, conveyance, keeping, storage, processing and packing of orthodox medicines, complementary medicines, medical devices, veterinary medicines and Scheduled substances, and the manner in which orthodox medicines, complementary medicines, veterinary medicines, device and Scheduled substances must be kept and controlled in different categories of hospitals;

(x) prescribing the method in accordance with which samples may be taken under this Act and the form of the certificates to be issued by the inspectors in respect of such samples;

(y) 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;

(z) authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, storage, transportation, sale or use of any medical device or class of medical devices or orthodox medicines, complementary medicines or veterinary medicines in respect of its safety, quality and efficacy;

(zA) with regard to any matter to ensure the safety, quality and efficacy of orthodox medicines, complementary medicines, veterinary medicines, and medical devices;

(zB) as to the summary seizure and disposal of any Scheduled substance found in the possession or custody of any person not entitled under this Act to keep or use it;

(zC) as to the disposal or destruction of a Scheduled substance which has become unfit for use, and the report to be furnished in respect thereof;

(zD) regarding the fees to be paid to the Authority in respect of an application for the registration, and in respect of the registration of an orthodox medicine, complementary medicine, veterinary medicine, Scheduled substance or medical device the fee to be paid annually to the Authority in respect of the retention of the registration of an orthodox medicine, complementary medicine, veterinary medicine, Scheduled substance or medical device and the date on which such annual fee must be paid;

(zE) regarding the fee payable in respect of the authorisation of the use of unregistered orthodox medicines, complementary medicines or veterinary

medicines, the issuing of any licence under this Act, or renewal of any license under this Act, the performance of inspections to assess the quality of orthodox medicines, complementary medicines, veterinary medicines, Schedule substances or medical devices for purpose of registration and the evaluation of changes to the particulars contained in registers;

(zF) relating to appeals against decisions of the Director-General or the Authority;

(zG) relating to the conditions under which orthodox medicines, complementary medicines, veterinary medicines or Scheduled substances may be sold;

(zH) relating to the re-packaging of orthodox medicines, complementary meditines or veterinary medicines, in patient ready packs;

(zI) relating to the scientific, pharmaceutical clinical and other skills required by members of the Authority or any committee of the Authority or by a member of the executive committee of the Authority to evaluate the quality, efficacy and safety of orthodox medicines, complimentary medicines, medical devices or veterinary medicines;

(zJ) relating to the safety, quality and efficacy of imported orthodox medicines, complementary medicines, medical devices or veterinary medicines;

(zK) relating to the control and conduct of clinical trials: and

(zL) any other matter not inconsistent with this Act.

(2) The Minister must, not less than 3 months before any regulation is made under subsection (1), cause the text of such regulation to be published in the *Gazette*, together with a notice declaring the Minister's intention to make that regulation and invite interested persons to furnish the Minister with any comments thereon or any representation they may wish to make in regard thereto.

(3) Subsection (3) does not apply in respect of–

(a) any regulation which, after that subsection has been complied with, has been amended by the Minister in consequence of comments or representations received by the Minister in pursuance of the notice issued thereunder;

(b) any regulation in respect of which the Minister is, after consultation with the Authority, of the opinion that the public interest requires it to be made without delay.

(4) A regulation under subsection (1)*(zD)* and *(zL)* must be made only in consultation with the Minister of Finance.

(5) Regulations made under subsection (1)(k) may prescribe that any orthodox medicine, complementary medicine, medical devices, veterinary medicine, or any component thereof must comply with the requirements set out in any publication which in the opinion of the Authority is generally recognised as authoritative.

(6) Regulations may be made under this section in respect of particular orthodox medicines, complementary medicines, veterinary medicines, or Scheduled substances or classes or categories of orthodox medicines, complementary medicines, medical devices, veterinary medicines, or Scheduled substances, or in respect of orthodox medicines, complementary medicines, veterinary medicines, or Scheduled substances other than particular classes or categories of orthodox medicines, complementary medicines, veterinary medicines or Scheduled substances, and different regulations may be so made in respect of different orthodox medicines, complementary medicines, veterinary medicines or Scheduled substances or different classes or categories of orthodox medicines, complementary medicines, veterinary medicines or Scheduled substances.

(7) Any regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith and a fine, or imprisonment, not exceeding the maximum penalty provided for in section 42.

(8) Despite the provisions of subsection(1), the Minister may, if the Minister deems it to be in the public interest, after consultation with the Board or the Executive Committee thereof, make regulations relating to any matter referred to in subsection (1).

Act binds State

49. This Act binds the State.

Repeal and amendment of certain sections and savings

50. (1) Subject to subsection (2)—

(a) the laws mentioned in Schedule 1 are hereby repealed to the extent set out in that Schedule; and

(b) the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of' 1947), specitied in Schedule 2 is hereby amended to the extent set out in that Schedule.

(2) At the commencement of this Act—

(a) anything done in terms of the repealed Medicines and Related Substances Control Act, 1965, and the Medicines and Related Substances Control Act (Transkei), 1978; and the amended provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947. in respect of stock remedies prior to the commencement of this Act, is deemed to have been clone in terms of this Act;

(b) permits , licences or certificates issued by the Medicines Control Council or any body in terms of the provisions of the Medicines and Related Substances Control Act, 1965, or by any body in terms of the Medicines and Related Substances Control Act (Transkei), 1973, prior to such commencement is deemed to be permits, licences or certificates of registration granted by the Authority in terms of this Act: and

(c) permits, licences or certificates of registration issued in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947, in respect of stock remedies, prior to such commencement is deemed to be permits, licences or certificates of registration in respect of veterinary medicines granted by the Authority in terms of this Act.

(3) Subject to this Act, the Registrar appointed in terms of the Medicines Act must act as the Chief' Executive Officer until a day immediately preceding the day on which a Chief Executive Officer is appointed in terms of section 16.

(4) Subject to this Act, the Medicines Control Council established by section 2 of the Medicines Act must perform the functions of the Board until a day immediately preceding the day on which the Minister appoints the Board in terms of section 6.

(5) Any officer or employee of—

(a) the Department of Health's Directorate. Medicines Administration, which provides support to the said Medicines Control Council, may act as a staff member of the Authority until a date determined by the Director-General of Health; and

(b) the Department of Agriculture perform ng on a full-time basis functions regarding stock remedies may act as a staff member of the Authority until a date determined by the Director-General of Health, acting in consultation with the Director-General of Agriculture.

Repeal of certain laws

51. All laws which formed part of the legislation of the Republics of Transkei, Bophuthatswana, Venda and Ciskei and those laws which formed part of the legislation of the self-governing territories of Lebowa, Gazankulu, Qwaqwa, KwaZulu, KwaNdebele and KaNgwane in terms of the National States Constitution Act, 197 I (Act No 2 I of 1971), must, to the extent that they deal with matters provided for in this Act, be deemed to be repealed.

Operation of Act in relation to other laws

52. This Act is in addition to and not in substitution for any other law which is not in conflict with or inconsistent with this Act.

Continuation of Regulations and Schedules of substances determined in terms of Medicines Act

53. (1) Subject to this Act, all Regulations made in terms of the Medicines Act and any Schedules of substances which had been determined in terms of the Medicines Act remain, subject to any repeal or amendment by a competent authority, in force.

(2) Subject to this Act, all Regulations made in terms of the Stock Remedies Act and any Schedules determined in terms of the Stock Remedies Act in respect of stock remedies remain, subject to any repeal or amendment by a competent authority, in force.

(3) Despite subsection (1), but subject to subsection (4), Schedules 1 up to and including Schedule 9 of the Medicines Act, are hereby repealed.

(4) Any reference in any law or document to any medicine or substance referred to in any Schedule to the Medicines Act prior to the date of commencement of this Act, must be construed from that date as a reference to the corresponding medicine or other substance prescribed by the Minister under section 31.

Amendment of Schedules

54. The Minister may, on the recommendation of the Authority, by notice in the *Gazette* amend the Schedules referred to in section 53, by the inclusion therein or the deletion therefrom of any medicine or other substance, or in any other manner.

Short title and commencement

55. This Act is called the South African Medicines and Medical Devices Regulatory Authority Act, 1998, and comes into operation on a date determined by the President by proclamation in the *Gazette.*

SCHEDULE 1

REPEAL OF LAWS

(Section 50)

No. and year of law	Short title	Extent of repeal
Act No. 101 of 1965	Medicines and Related Substances Control Act, 1965	The whole, except sections 1, 15B, 18, 22B, 24, 34A and 40.
Act No. 90 of 1997	Medicines and Related Substances Control Amendment Act, 1997	The whole, except sections 1, 10, 12, 14, 15, 22, 26, 28, 31 and 33.
Act No. 27 of 1978 (Transkei)	Medicines and Related Substances Control Act, 1978	The whole.

SCHEDULE2

No. and year of law	hurt title	Exten of Amendment
Act No. 36 of 1947	ertilizers, Farm Feeds, agricultural Remedies nd Stock Remedies Act, 947	The amendment of section 1 of Act 36 of 1947 as amended by section 1 of Act 24 of 1947 and section 1 of Act 4 of 1980. 1. Section 1 of Act 36 of 1947 is hereby amended— *(a)* by the substitution for the definition of "advertisement" of the following definition: "advertisement" means any written, illustrated, visual or other descriptive material or oral statement, communication, representation or reference distributed to members of the public or brought to their notice in any other manner and which is intended to promote the sale of fertilizers, farm feeds, agricultural remedies [or stock remedies] or encourage the use thereof or draw attention to the nature, properties, ldkiil)t:lgest)r~lses thereof, and "advertise" has a corresponding meaning;"; *(b)* by the substitution for the definition of "establishment" of the following definition: "establishment", in relation to a fertilizer, farm feed, or agricultural remedy [or stock feed], means the premises where such fertilizer, farm feed, or agricultural remedy [or stock feed] is manufactured, controlled, packed, marked or labelled for the purposes of sale; and *(c)* by the substitution for the definition of "registrar" of the following definition: "registrar" means the Registrar of Fertilizers, Farm Feeds, and Agricultural Remedies land Stock Remedies] designated in terms of section 2, and includes an officer acting under a delegation from or under the control or direction of the registrar.
		The substitution of section 2 of Act 36 of 1947 as amended by section 2 of Act 60 of 1970 and substituted by section 2 of Act 24 of 1977. 2. The following section is hereby substituted for section 2 of Act 36 of 1947: "Designation of registrar 2.(I The Minister shall designate an officer in the Department of Agricultural Technical Services as the Registrar of Fertilizers, Farm Feeds, and Agricultural Remedies [and Stock Remedies] who shall, subject to any instructions issued by the Minister, exercise the powers, perform the functions and carry out the duties conferred upon, assigned to or imposed upon the registrar under this Act (2) ( ) Any power conferred upon, function assigned to or duty imposed upon the registrar may be exercised, performed or carried out by an officer under a delegation from or under the control or direction of the registrar.

No. and year of Law	Short title	Extent of Amendment
		(b) Any decision made or instruction issued by any such officer may be withdrawn or amended by the registrar, and shall, until it has been so withdrawn or amended, be deemed, except for the purposes of this paragraph, to have been made or given by the registrar,'"
		The substitution of section 3 of Act 36 of 1947 as amended by section 3 of Act 60 uf 1970, section 3 of Act 24 of 1977 and section 2 of Act 4 of 1980. 3. The following section is hereby substituted for section 3 of Act 36 of 1947: "Registration of fertilizers, farm feeds, agricultural remedies, sterilizing plants and pest control 3.(1) *(a)* Application for registration of a fertilizer, farm feed, agricultural remedy, [stock reined}], sterilizing plant or pest control operator shall be made to the registrar in the prescribed manner and shall be accompanied by the prescribed application tee. *(b)* Any person applying for registration in terms of paragraph *(a)* shall supply or make available to the registrar, in the manner and at the time and place that he or she determines. the samples and particulars that he requires. (2) If, after consideration of any such application and after such investigation and enquiry as he or she may deem necessary, the registrar is satisfied that — *(a)* the fertilizer, farm feed, or agricultural remedy [or' stock remedy] in respect of which registration is applied for is suitable and sufficiently effective for the purposes for which it is intended. and complies with such requirements as may be prescribed, and that it is not contrary to the public interest that it be registered. and that the establishment where it is manufactured is suitable for such manufacture. he or she shall register such fertilizer, farm feed or agricultural remedy [or stock remedy]; – *(b)* the sterilizing plant in respect of which registration is applied for is suitable and sufficiently effective for the purpose for which it is intended, and complies with such requirements as may be prescribed, and that it is not contrary to the public interest that such sterilizing plant be registered, he or sbe shall register such sterilizing plant; *(c)* the pest control operator in respect of whom registration is applied for has the prescribed Qualifications or is otherwise, to such extent as may be determined by the registrar, skilled in the use of agricultural remedies, and that it is not contrary to the public interest that such pest control operator be registered, he or she shall register such pest control operator:

No. and year of Law	Short title	Extent of Amendment
		Provided that the registrar may refuse an application for registration of a fertilizer, farm feed, agricultural remedy, [stock remedy], sterilizing plant or pest control operator if any previous registration of such fertilizer, farm feed, agricultural remedy, [stock remedy], sterilizing plant or pest control operator has been cancelled under section 4. (3) Any registration under this section shall be subject to the prescribed and any additional conditions as may be determined by the registrar and shall be valid for such period as may be prescribed and the registrar shall issue in respect of such registration a certificate of registration to the person applying therefor. (4) (a) Any registration under this section may be renewed when the period for which it is valid has lapsed. (b) The provisions of subsections (1), (2) and (3) shall *mutatis mutandis* apply to the renewal of *any* registration."
		The substitution of section 4 of Act 36 of 1947 as substituted by section 4 of Act 60 of 1970, section 4 of Act 24 of 1977 and amended by section 3(c) of Act 2 of 1980 4. The following section is hereby substituted for section 4 of Act 36 of 1947: "Cancellation of registration 4. (1) The registrar may cancel the registration of any fertilizer, farm feed, or agricultural remedy [or stock remedy] at any time if he or she is satisfied— (a) that a person has in connection with the registration concerned contravened or failed to comply with a provision of this Act; (aA) that a person has contravened or failed to comply with a condition to which the registration concerned is subject; (b) that such fertilizer, farm feed, or agricultural remedy [or stock remedy] is not of the composition, nature and efficacy specified in the application for registration thereof, or does not possess the chemical, physical and other properties so specified and does not comply with any requirements that may be prescribed; (c) that the practices followed and facilities available at or in respect of the establishment or the operation of the undertaking at such establishment are not suitable for the manufacture of the fertilizer, farm feed, or agricultural remedy [or stock remedy] concerned; (d) that the person managing such undertaking does not have sufficient knowledge of the relevant provisions of this Act or of the practices to be followed in the operation of such undertaking; (e) that it is contrary to the public interest that such fertilizer, farm feed, or agricultural remedy [or stock remedy] shall remain registered; or

No. and year nf Law	hort title	Extent of Amendment
		(f) that any incorrect or misleading advertisement is used in connection with such fertilizer. farm feed, or agricultural remedy [or stnck remedy]. (2) The registrar may cancel the registration of any sterilizing plant at any time if he or she is satisfied that— *(a)* a person has in connection with the registration concerned contravened or failed to comply with a provision of this Act: *(b)* a person has contravened or failed to comply with a condition to which the registration concerned :; subject: *(c)* the sterilizing plant dries not comply with the prescribed conditions or is otherwise not effectively equipped for the sterilization of the substances referred to in the definition of "sterilizing plant"; **(d) it s contrary to the public interest that the sterilizing plant shall remain registered.** (3) The registrar may cancel the registration of any pes control operator at any time if he or she is satisfied that— *(a)* the pest control operator has contravened or failed to comply with a provision of this Act or a condition of his registration: *(b)* the pest control operator has failed to comply with an order issued under section 6A; *(c)* it is contrary m the public interest that the pest control operator shall remain registered. "
		The substitution of section 4A of Act 36 of 1947 as inserted by section 5 of Act 24 of 1977 and amended by section 4*(a)* and *(c)* of Act 4 of 1980 5. The following section is hereby substituted for section 4A of Act 36 of 1947: "Availability, lapse and return of certificate of registration 4A. (1) The person to whmn a certificate of registration has been issued in terms of section 3(3) shall— *(a)* in the case of a fertilizer. farm feed, or agricultural remedy [err stock remedy]. cause that certificate of registration or a copy thereof to he available for inspection by the registrar at all times at the establishment where such fertilizer. farm feed, or agricultural remedy [or stock remedy] is manufactured; or *(b)* in the case nf a sterilizing plant or a pest control operator, produce that certificate of registration or a copy thereof to the registrar when he or she is so requested. (2) The registration of any fertilizer. farm feed, or agricultural remedy [or stock remedy] and the certificate of registration issued in respect of such registration shall lapse— *(a)* if he person to whnm that certificate of registration has been issued, ceases to manufacture or sell the fertilizer. farm feed. or agricultural remedy 'or stock remedy] in question: or *(b)* if he establishment in question is no longer used for the manufacture of such fertilizer. form feed. agricultural remedy or stock feed.

No. and year of Law	Short title	Extent of Amendment
		(2A) The registration of any sterilizing plant and the certificate of registration issued in respect of such registration shall lapse if the registered plant ceases to be used as a sterilizing plant. (29) The registration of any pest control operator and the certificate of registration issued in respect of such registration shall lapse if the registered person ceases to be a pest control operator. (3) When the registration of any fertilizer, farm feed, agricultural remedy, [stock remedy], sterilizing plant or pest control operator has lapsed in terms of subsection (2), (2A) or (29) or has been cancelled in terms of section 4, the certificate of registration in question shall, within the prescribed period, be returned to the registrar by the person to whom it was issued. "
		The sub-titution of section 7 of Act 36 of 1947 as substituted by section 5 of Act 60 of 1970 and section 8 of Act 24 of 1977 6. The, following section is hereby substituted for section 7 of Act 36 of 1947: "Sales of fertilizers, farm feeds, and agricultural remedies 7. (1) No person shall sell any fertilizer, farm feed. or agricultural remedy [or stock remedy] unless— (a) it is registered under this Act under the name or mark under which it is so sold: Provided that a fertilizer, farm feed, or agricultural remedy [or stock remedy] in respect of which the period of validity of the registration has expired, the certificate o registration has been cancelled in terms of section 4 or has lapsed in terms of section 4A (2) and which, before or on the date of such cancellation or lapse, was no *longer* under the control of, or owned by the person to whom that certificate of registration was issued, may, subject to the provisiors of section 7*bis*, be sold; (b) it is, subject to the provisions of paragraph (c), packed in such manner and mass or volume as may be prescribed; (c) the container in which it is sold, complies with the prescribed requirements and is sealed and labelled or marked in such manner as may be prescribed or, if it is not sold in a container. it is accompanied by the invoice referred to in section 9; and

No. and year of Law	Short title	Extent of Amendment
		(d) it is of the composition and efficacy specified in the application for registration thereof, possesses all chemical, physical and other properties so specified, and complies with the prescribed requirements. (2) *(a)* No person shall for reward or in the course of any industry, trade or business— (i) use, or recommend the use of, any agricultural remedy [or stock remedy] for a purpose or in any manner other than that specified on the label on a container thereof or described on such container; (ii) use any agricultural remedy unless he is a pest control operator registered in terms of this Act or otherwise than in the presence and under the supervision of a pest control operator so registered, [*(b)* The provisions of paragraph *(a)* shall, in the case of a stock remedy, not apply to a veterinarian registered under the Veterinary Act, 1933 (Act 16 of 1933).]"
		The substitution of section 7*bis* of Act 36 of 1947 as inserted by section 1 of Act 4X of 1950 and substituted by section 6 of Act 60 of 1970 and section 9 of Act 24 of 1977. 7. The following section is hereby substituted for section 7*bis* of Act 36 of 1947: "**Prohibition on acquisition,** disposal, sale or use of certain fertilizers, farm feeds, and agricultural remedies 7*bis* (1) The Minister may by notice in the *Gazette*— *(a)* prohibit the acquisition, disposal, sale or use of fertilizers, farm feeds, or agricultural remedies [or stock remedies]; or *(b)* prohibit such acquisition, disposal, sale or use, except in accordance with such conditions as may be specified in the notice or except under the authority of and in accordance with such conditions as may be specified in a permit issued by the registrar, and may in like manner repeal or amend any such notice. (2) Any prohibition issued under subsection (1) may apply— *(a)* throughout the Republic or in one or more specified areas; *(b)* to any person or to persons belonging to any specified class or group of persons or to persons other than persons belonging to any such class or group of persons; or *(c)* in respect of all or one or more classes or kinds of fertilizers, farm feeds, or agricultural remedies [or stock remedies]. (3) Any condition referred to in subsection (1) shall not be subject to any limitations of whatever nature, and such conditions may differ in respect of different areas, persons or classes or groups of persons."

and year of Law	hort title	dent of Amendment
		ıe substitution of section 9 of' Act 36 of 1947 as ıended by section 7 of Act 60 of 1970 and sec-ın 10 of Act 24 of 1977. 8. The following section is hereby substituted r section 9 of Act 36 of 1947: Invoices required in case of sale of fertilizers, rm feeds, agricultural remedies not in a con-iner 9. An/ person whn sells any fertilizer, farm ed, or agricultural remedy [or stock remedy] ot in a container, shall give to the purchaser at ıe time of delivery or send to him at the time of espatchan invoice setting forth such particulars ı respec of such fertilizer, farm feed. or agricul-ıralremedy [or stock remedy] as may be pre-cribed.
		he substitution of section 13 of Act 36 of 1947 s substituted by section 8 of Act 60 of 1970. 9. The following section is hereby substituted or section 13 of Act 36 of 1947: Exclusion of any fertilizer, farm feed, or agri-cultural remedy from operation of Act 13. The Minister may by notice in the *Gazette* xclude, subject to such conditions as he or she nay dete mine, any fertilizer, farm feed. or agri-ulturalremedy [or stock remedy] from the op-eration of any or all of the provisions of this Act."
		The substitution of section 14 of Act 36 of 1947 as amended by section 35 of Act 28 of 1961. and substituted by section 9 of Act 60 of 1970 and section 1. I of Act 24 of 1977. 10. The following section is hereby substituted for section 14 of Act 36 of 1947: "Designation of technical advisers and analyst 14. For the purpose of this Act, the Minister may fron time to time designate persons, includ-ing officers, as— *(a)* technical advisers who shall advise the reg-istrar in regard to matters referred to them by the registrar: and *(b)* analysts to analyse samples of fertilizers, farm feed;, or agricultural remedies [or stock remedies referred to them by the registrar. and to report the reon in the form and manner pre-scribed."'

No. and year of Law	Short title	Extent of Amendment
		The substitution of section 15 nf Act 36 of 1947 as amended by section 36 of Act 28 of 1961. section 10 of Act 60 of 1970 and substituted fry section 14 of Act 24 of 1977 II, The following section is hereby substituted for section 15 of Act 36 of 1947: "Power of entering premises, examinations, analysis of samples, and seizure 15. (1) The registrar acting on the authority of and in accordance with a warrant issued under section 15A may at any reasonable time— (a) enter upon or enter and inspect any place, premises or vehicle in respect of which he or she on reasonable grounds believes that on or in it there is manufactured, processed. treated, prepared, graded, classified, packed, marked, labelled. held, bottled, removed, transported. exhibited. sold or used any fertilizer, farm feed, or agricultural remedy and examine or test any such fertilizer. farm feed, agricultural remedy or any ingredient thereof; (b) examine any book or document on or in any place, premises rrr vehicle referred to in paragraph (a) in respect of which he or she believes on reasonable grounds that it relates to any fertilizer, farm feed. agricultural remedy, or an ingredient thereof. and make copies nf or extracts from such book or document; (c) examine any operations or processes carried out at any place or premises referred to in paragraph (a) in connection with the manufacture, processing, treatment, preparation, grading, classification, packing, marking, labelling, holding, bottling, removal, transport. exhibition, selling or use of' any fertilizer. farm feed. or agricultural remedy and demand from the person in charge of such operations or processes, or the owner of or the person having the custody of any fertilizer, farm feed or agricultural remedy or an ingredient thereof, any relevant information or explanation relating to any such operations or processes, or fertilizer, "arm feed, agricultural remedy, or ingredient; (d) demand from the owner or any person having the custody of any book or document referred to in paragraph (b) an explanation relating to any record or entry therein; (e) seize any book, document. fertilizer, farm feed. or agricultural remedy which may furnish proof of an offence in terms of this Act, or any quantity of any fertilizer. farm feed, or agricultural remedy in respect of which there is reason to believe that any such offence has been committed, and remove from or leave on or in the place, premises or vehicle in question, any book, document. fertilizer, 'arm feed, or agricultural remedy or any quantity thereof, which has so been seized. and

No. and year of Law	Short title	Extent of Amendment
		may in t is discretion place on such book, document, fetilizer, fro-m feed, or agricultural or the container thereof, such identification mark or seal as he may deem necessary; (f) take samples m cause samples to be taken of any fertilizer, farm feed, agricultural remedy, or an ingredient thereof, and open any container which contains or is suspected to contain anything used or intended for use in the manufacture, processing, treatment, preparation, grading, classification, packing, marking, labelling, holding, bottling, removal, transport, exhibition or sale of any fertilizer, farm feed, or agricultural remedy and examine, analyse, grade or classify such samples, or cause such samples to be examined, analysed, graded o classified. (2) Where the registrar carries out any examination in terms of subsection (1) in the presence of any person affected thereby, he or she shall first produce his or her written authority to such person. (3) Any sample taken in terms of subsection (1) shall— (a) be taken in accordance with tbe prescribed method; (b) be taken in the presence of the owner or the person having the custody of that fertilizer, farm feed, agricultural remedy, [stock remedy] or ingredient thereof, 01-. if such owner or person is nut available in the presence nf any other witness: and (c) in he presence of such owner or person, or such witness, be divided into three parts, and each part shall be packed in a suitable container and sealed with a seal and be labelled or marked in such manner as the nature thereof permits, so that such sample may be readily identified. (4) One part each of the sample which has been thus divided shall— (a) be handed or forwarded by registered post to such owner or person; (b) together with a certificate in the prescribed form be forwarded to an analyst who shall as soon as practicable test, examine or analyse the said part in accordance with the methods which the registrar may determine, and the result of such test, examination or analysis shall be recorded by such analyst on the prescribed form and be submitted to the registrar; and (c) be retained by the registrar. (5) The owner of anything from which any sample referred to in subsection (1)(f) was taken, may claim from the registrar an amount equal to the market value of such sample." (6) Subject to section 15A(l) the registrar may, during the day, without a warrant enter upon and examine any place, premises or vehicle after having identified himself or herself and in accordance with section 15 exercise the powers of seizure, removal, detention, collecting evidence and search (except the power to search any person), if—

No. and year of Law	Short title	Extent of Amendment
		(a) the person who is competent to consent to the entry and to such search, seizure removal and detention, gives that consent: or (b) the registrar on reasonable grounds believes matter- (I) the required warrant will be issued to him or her in terms of section 15A if he or she were to apply for the warrant; and (ii) the delay that would ensue by first obtaining the warrant would defeat the object or purpose of the entry, search, seizure, removal, detention, collection of evidence and other steps. (7) Subsection (6)(b) does nut serve as authority for, and may not be applied for the purpose of, entering and searching any private dwelling, nor for corralcting such seizure and removal, the collection o evidence and the taking of the said other steps therein."
		Insertion of section 15A in Act 36 of 1947 11. The following section is hereby inserted after section 15 of Act 36 of 1947: "**Provisions** relating to issue and execution of warrant 15A. ( ) The warrant contemplated in section 15 will be issued in chambers by any judge of the High Court or by a magistrate who has jurisdiction in the area where any fertilizer. farm feed, or agricultural remedy has been, or is being or is likely to be manufactured, processed, treated, prepared, graded, classified, packed, marked, labelled, held, bottled, removed, transported, exhibited, sold or used, and will be only issued if it appears to the judge or magistrate from information on oath or affirmation that there are reasonable grounds for believing that any fertilizer, farm feed, or agricultural remedy has been, or is being or is likely to be manufactured, processed, treated, prepared, graded, classified, packed. marked, labelled, held, bottled, removed, transported, exhibited, sold or used, and tbe registrar seeking the warrant may be asked to specify which of he powers contemplated in section 15A is or are likely to be exercised. (2) A warrant in terms of this section may be issued on any day and will be in force until— (a) it has been executed; or (b) it is cancelled by the judge or magistrate who issued it, or, if not available, by any other judge, or by any other magistrate with similar authority; or (c) the expiry of one month from the day of its issue; or (d) the purpose for which the warrant was issued. no longer exists whichever may occur first.

No. and year of Law	Short title	Extent or Amendment
		(3) A warrant issued in terms of this section may be executed by day only, unless the person who has issued the warrant has authorised the execution thereof by night at times which must be reasonable, and the entry upon or into and search of any place, premises or vehicle specified in the warrant, and the search of any person thereat, thereon or therein, must be conducted with strict regard to decency and order, including— (a) a person's right to, respect for and protection of his or her dignity; (b) the right of a person to freedom and security of his or her person; and (c) the right of a person to his or her personal privacy. (4) The registrar executing a warrant in terms of this section must immediately before commencing with the execution thereof— (a) identify himself or herself to the person in control of the place, premises or vehicle to be entered upon or entered, if that person is present, and hand to that person a copy of the warrant, but if no such person is present he or she must affix a copy of the warrant, to a prominent spot at, on or to the place, premises, or vehicle; (b) furnish that person at his or her request with particulars regarding the registrar's authority to execute such warrant; (c) for the purpose of paragraph (b) the registrar may be requested to produce the certificate issued in respect of him or her under section 26. (5) The registrar may use such force as may be reasonably necessary to overcome any resistance to entry and search. (6) The registrar may enter upon or enter, and search any place, premises or vehicle, and may search any person thereat, thereon or therein, only if he or she audibly has first demanded access thereto and has notified the purpose of the entry, unless the registrar on reasonable grounds believes that any fertilizer, farm feed or agricultural remedy book or document which is the subject of a search may be tempered with, destroyed or be lost if access is first demanded and that purpose notified. (7) If, during the execution of a warrant in terms of this section, a person claims that any goods, document, book or article found at, on or in the place, premises or vehicle in question contains privileged information and refuses the inspection or removal thereof, the registrar is executing the warrant, if of the opinion that the goods, document book or article may be relevant-

No. and year of Law	Short title	Extent of Amendment
		to and necessary for the investigation of any complaint or any alleged or suspected manufacturing, processing, treatment, preparation, grading, classification, packaging, marking, labelling, holding, removal, transportation, exhibition, sale, or use may be required to and necessary for the investigation of any complaint, must request the registrar of the High Court having jurisdiction, or the registrar's deputy, to seize and remove such goods, documents, drinks or articles for safe custody until the court has made a ruling on the question whether or not the information in question is privileged. (X) In undertaking any search for and inspection and seizure of suspected goods, documents, hooks or articles the registrar may be assisted by the complainant (if any) or any knowledgeable person in identifying any fertilizer, farm feed, or agricultural remedy. (9) No answer given or statement made by any person to the registrar exercising his or her powers in terms of section 15(1)(c) and *(d)* or given or made to the registrar exercising like powers by virtue of section 15(6) will, if self-incriminating, be admissible as evidence against that person in criminal proceedings instituted in any court against him or her. (10) The provisions of subsection (2) regarding the manner in which a search must reconducted, and subsections (4). (5), (6). (7) and (8) shall apply *mutatis mutandis* to the registrar acting by virtue ufs section 15(6).”'.
		The substitution of section 160 f Act 36 of 1947 as amended by section 37 of Act 28 of 1961, section 2 of Act 17 of 1972 and substituted by section 15 of Act 24 of 1977 12. The following section is hereby substituted for section 160 f Act 36 of 1947: “Import of fertilizers, farm feeds, and agricultural remedies **16.** (1) No person shall import any fertilizer, farm feed, or agricultural remedy [or stock remedy] into the Republic unless— *(a)* such fertilizer, farm feed, or agricultural remedy [o-stock remedy] is registered in terms of this Act is of the composition and efficacy specified in the application for registration thereof, possesses all chemical, physical and other properties so specified and complies with the requirements prescribed in respect thereof and is packed in a sealed container which is marked or labelled in the prescribed manner with the prescribed particulars: *(b)* in the case of a fertilizer or farm feed containing bone or any other substance derived from the carcass of an animal, a permit referred to in section 12 has been issued in respect thereof.

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		(2) Not withstanding the provisions of subsec-on **(1) th** registrar may, **in his or her discretion** id on su.h conditions as he or she **may deter-**iine, **in** writing **permit the import of any** con-gnment of any fertilizer. farm feed. or agricul-iralreme dy [or stock remedy] **which does not** omply with **the requirements referred to in** sub-ection **(1** *(a).* (3) **Fertilizers. farm feeds,** or agricultural rem-**dies** [or stock remedies] **imported** shall— *(a)* only **be imported through a prescribed port** r place; *(b)* **if a** sample **thereof** has **thus been** taken, **not e sold m the Republic except on the written** au-nority **of 'he** registrar **and subject to the** condi-ions spec fied **therein.** (4) The provisions of section 15 relating to amples shall *mutatis mutandis* apply **with** refer-nce **to a simple taken in terms 01** this **section.** (5) If any **fertilizer, farm** feed, or agricultural emedy **[or** stock remedy]. which in terms of ubsection **(3)** *(b)* may not **be** removed from a ort **or** pla e, **is found to comply with the** require-ments **of** this **Act, no** rent charges **shall be** pay-ble **by** the importer **in respect of the period in** which **it** could **not be** so **removed. or where the** Railways, **administration** is **required to deliver or** o **forward that fertilizer,** farm feed, or agricultural emedy **[o** stock remedy], **in respect of any** por-**ion of the period in question which is subsequent** o **the pres** ntation to **the Railways Administration** of a delive **y order, or** a **forwarding order.** as the ase **may l** e. **(6)** *(a)*, **f** any **fertilizer, farm feed. or agricu-**turalreme **y [or** stock remedy] has been im-ported con rary to **the** provisions of **this section.** such fertili er, **farm feed,** or **agricultural remedy [or** stock remedy] shall at the **option of the** im-porter ther of— **(i)** at th e **expense nf such importer be** re-moved **by** him **or her from the Republic within such** perio **as the registrar may determine: or** **(ii) be** forfeited to **the** State **and be either** de-stroyed **or** otherwise **disposed of as the registrar may direct and if such importer fails to remove such** fertili er, farm **feed,** or agricultural **remedy** [or stock remedy] **in terms of the provisions of** subparagra h *(i)* **within the period referred to in that** subpa agraph, **it** shall **be forfeited to the State,** and **e either destroyed or otherwise dis-posed** of as **the registrar may direct.**

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		(b) An, costs incurred by the State in connection with .he destruction or disposal of any fertilzer, farm feed. or agricultural remedy [or stock emedy] n terms of the provisions of paragraph (a), may e recovered from the importer conmed. "
		ne substitution of section 18 of Act 36 of 1947 amend.d by section 2 uf Act 48 of 1950. section 38 of Act 28 of 1961. section 11 of Act 60 of)70, section 16 of Act 24 of 1977 and section (b) of A t 4 of 1980 13. Th following section is hereby substituted or section 18 of Act 36 nf 1947: **Offence**; and penalties 18. (1) Any person who— (a) fail, to comply with the provisions of section 9; (b) obs ructs or hinders the registrar, any technical advi ser or any analyst in the exercise of his r her powers or performance of his or her duties rider this Act: (bA) fails to make any statement or give any xplanation if be is requested thereto by the registrar in the exercise of his powers or the performance of his duties under this Act: (bB) fa Is to comply with an order issued under ection 6A; (c) cmr ravenes or fails to comply with the provisions of section 7, 8, 10, 12 or 16 or with any condition contemplated in section 3 (3). 16 (2) or 16 (3) (d). (c)bis acquires, disposes of, sells or uses fertilzers, farm feeds, or agricultural remedies [or stock ren edies] contrary to a prohibition issued under sec.ion 7bis; (e) tampers with any sample taken in terms of this Act, or with anything seized in terms of this Act; (f) mak es use, in connection with any fertilizer, farm feed, or agricultural remedy [or stock remedy], of any certificate. invoice or other document issued in espect of any other fertilizer, farm feed, or agricultural reined y [or stock remedy], or which is no longer valid; (g) makes any false or misleading statement in connection with any fertilizer, farm feed. or agricultural re reedy [or stock remedy]— (i) in an application for the registration thereof; (ii) in any invoice issued in terms of section 9; (iii) in any advertisement thereof; (iv) in the course of the sale thereof; (v) in an application for a permit refereed to in section 7bis (1)(h); (vi) in a notice referred to in section 10; (vii) if he acts in accordance with the provisions of section 16 (1)(b):

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		(h) sells ny fertilizer, farm feed, or agricul-ural reined; [or stock remedy] upon the con-iiner of which a false or misleading statement in onnection with such contents is printed or writ-:n; *(i)* sells any fertilizer, farm feed, or agricultural emedy [or stock remedy] which is not of the ind, nature composition, strength, potency or uality desc ribed or represented when so sold: *(j)* having been duly summoned in terms of ection 6 (4 *(a)* to appear before the board, fails ithout lawful excuse so to appear; *(k)* having appeared as a witness before the oard, refuses without lawful excuse to be sworn to make affirmation or to produce any docu-ent or answer any question which he or she may e lawfully required to produce or answer; *(l)* fails to comply with the provisions of sec-on 4A (1) or (3), iall be guilty of an offence and liable on convic-m - (i) in the case of a contravention under para-raph *(a), (c), (bA)* or *(l)* to a fine not exceeding ve hundred rand or imprisonment for a period ot exceeding twelve months or to both such tine nd such imprisonment; and (ii) in the case of a contravention under para-mph (bB), 'c), *(c)bis, (e), (f), (g), (h), (i), (j)* 'r k) to a fine not exceeding one thousand rand or nprisonment for a period not exceeding two ears or to both such fine and such imprisonment. (2) The court convicting any person of an of-ence under this Act, may, upon the application of ire prosecutor, declare any fertilizer, farm feed, or gricultural remedy [or stock remedy] in respect f which the offence has been committed and all ertilizers, farm feeds, or agricultural remedies [or tock remedies] of a similar nature to that in re-pect of wh ch such person has been convicted, nd of whit such person is the owner, or which re in his possession, to be forfeited to the State. (3) All fertilizers, farm feeds, or agricultural emedies [o stock remedies] forfeited under this Act shall be destroyed or otherwise dealt with as he Minister may direct."
		rhe substitu ion of section 20 of Act 36 of 1947 as amended by section 39*(a)* of Act 28 of 1961 and section 7 of Act 24 of 1977 14. The f allowing section is hereby substituted for section 20 of Act 36 of 1947: "Procedure and evidence 20. (1) In my criminal proceedings under this Act—

No. and year of Law	Short title	Extent of Amendment
		(a) any quantity of a fertilizer, farm feed, or agricultural remedy [or stock remedy] in or upon any premises, place, vessel or vehicle at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary be proved, be deemed to be of the same composition, to have the same degree of efficacy and to possess in all other respects the same properties as that 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 an analysis or test carried out in pursuance of the provisions of sub-section (3) of section fifteen and purporting to be signed by the analyst who carried out such analysis or test shall be accepted as *prima facie* proof of the facts stated therein; *(d)* any statement or entry contained in any book or document kept by any manufacturer, importer or owner of a fertilizer, farm feed, or agricultural remedy [or stork remedy], or by the manager, agent or employee of such person, or found upon or in any premises occupied by, or any vehicle used in the business of such person, shall be admissible in evidence against him or her 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 person, or by any manager, agent or employee of such person 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 analysis or test performed in terms of the provisions of section fifteen or section sixteen, unless a copy of the analyst's certificate has been transmitted at least twenty-one days before the institution of such prosecution to the person who is to be the accused."
		The substitution of section 21 of Act 36 of 1947 as amended by section 40 of Act 28 of 1960, section 12 of Act 60 of 1970 and substituted by section 18 of Act 24 of 1977 15. The following section is hereby substituted for section 21 of Act 36 of 1947: "Special defence in case of prosecutions 21. It shall be a sufficient defence for a person charged with the sale of any fertilizer, farm feed, or agricultural remedy [or stock remedy] in contravention of section 7 (1) *(d)* if he or she proves to the satisfaction of the court— *(a)* that he purchased such fertilizer, farm feed, or agricultural remedy [or stock remedy] under a registered name or mark as being the same in all respects as the article which he purported to sell;

No. and year of Law	Short title	Extent of Amendment
		(b) that he or she had no *reason* to believe at the time of the sale that it was in any respect different from such article; *(c)* that he or she sold it in the original container and in the state in which it was when he or she purchased it: and *(d)* that the container thereof complied with the prescribed requirements and was sealed and labelled or marked in the prescribed manner with the prescribed particulars. " The substitution of section 22 of Act 36 of 1947 as amended by section 41 of Act 28 of 1961 and section 19 of Act 24 of 1977 16. The following section is hereby substituted for section 22 of Act 36 of 1947: "Acts or omissions by manager, agent or employee 22. (1) Whenever any manager, agent or employee of any manufacturer, importer or owner of a fertilizer, farm feed. or agricultural remedy [or stock remedy] does or omits to do any act which it would be an offence under this Act for such manufacturer, importer or owner to do or nmit to Jo, 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 manufacturer, importer or owner; and *(b)* all reasonable steps were taken by the manufacturer, importer or owner to prevent any act or omission of the kind in question; and *(c)* it was not under any condition or in any circumstance 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 manufacturer, importer or owner, as the case may be, shall be presumed himself or herself to have done or omitted to do that act and be liable to be convicted and sentenced in respect thereof; and the fact that he or she issued instructions forbidding any act or omission of the kind in question shall not, of itself. be accepted as sufficient proof that he or she took all reasonable steps to prevent the act or omission. (2) Whenever any manager, agent *or* employee of any such manufacturer, importer or owner does or omits to do an act which it would be an offence under this Act for the manufacturer, importer or owner to do or omit to do, he or she shall be liable to be committed and sentenced in respect thereof as if he or she were tbe manufacturer, importer or owner. *(3)* Any such manager. agent or employee may he so convicted and sentenced in addition to the manufacturer, importer or owner.
		The substitution of section 23 of Act 36 of 1947 as amended by section 42*(a)* of Act 28 of 1961, section 13 of Act 6 of 1970, section 20 of Act 24 of 1977 and section 9(0) of Act 4 of 1980

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		17. The following section is hereby substituted or section 23 of Act 36 of 1947: 'Regulations 23. (1) The Minister may make regulations— *(a)* prescribing the manner in which fertilizers, farm feeds, agricultural remedies, [stock remedies], sterilizing plants and pest control operators may be registered, the manner in which any such registration may be renewed and the information to be furnished and the fees to be paid with any application for registration and renewal of registration; *(b)* prescribing the description and conditions under which any substance may be registered, reported or sold as a fertilizer, farm feed, or agricultural remedy [or stock remedy] under any particular name or mark; *(c)* prescribing the manner in which and the time within which an appeal under section 6 [six] must be noted and prosecuted: *(d)* prescribing the particulars to be set forth in any invoice to be furnished under section nine; *(e)* prescribing the composition, efficacy, theroical, physical or other property required in respect of any substance in order that it may be imported, sold or registered as a fertilizer, farm feed, or agricultural remedy [or stock remedy]. as the case may be; *(f)* prescribing the limits within which any fertilizer, farm feed, or agricultural remedy [or stock remedy] may be deficient in any of its ingredients and the proportion in which any preservative, antiseptic or other constituent may be present therein; *(g)* prescribing requirements as to the mass and volume and containers in which fertilizers, farm feeds, or agricultural remedies [or stock remedies] shall be packed, the manner in which they shall be packed into such containers, the manner in which such containers shall be sealed and labelled or marked and the particulars which shall appear on such labels and containers; *(h)* prescribing the processes by which fertilizers, farm feeds, or agricultural remedies [or stock remedies], or substances used in the manufacture of fertilizers. farm feeds, or agricultural remedies or stock remedies] shall be sterilized, and the manner of inspection of sterilizing plants; *(hA)* prescribing the requirements with which any establishment shall comply, the practices which shall be followed in the operation of any undertaking at any establishment, the facilities which shall be available at any establishment, and the records to be kept and the information to be furnished in respect of any establishment and the operation of my undertaking at any establishment; *(hB)* prescribing the records to be kept and the returns to be rendered in respect of registered sterilizing plants:

No. and year of Law	Short title	Extent of Amendment
		(hC) prescribing the records to be kept and the returns to be rendered by registered pest control operators; *(i)* for preventing the adulteration of fertilizers. farm feeds, or agricultural remedies[or stock remedies] or the tampering with containers thereof; *(j)* prescribing the methods to be employed, the fees to be paid, and the certificates to be issued in respect of the examination, analysis or test of samples taken under this Act; *(k)* for preventing the use of false or misleading statements in advertise ments of fertilizers. farm feeds, or agricultural remedies [or stock remedies]; *(l)* requiring any person who has in his possession or under his or her control any fertilizers, farm feeds, or agricultural remedies [or stock remedies], to keep records relating thereto in the form and manner prescribed, and tcr render returns in the form and manner and at the times prescribed: *(m)* prohibiting the disposal. acquisition or use rrf any farm feed as a fertilizer; *(n)* in respect of any other matter under this Act which is to be prescribed, and generally for the efficient carrying out of the objects and purposes of this Act. **(2)** Different regulations may be made under this section n respect of different classes or kinds of fertilizer: farm feeds, agricultural remedies and stock remedies, and in respect of different kinds of establishments and different classes or groups of persons. **(3)** Any regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith, but not exceeding the maximum penalty prescribed by section 18 [eighteen]. (4) Befor any regulations are made under this section, such regulations shall be published by the Minister in he *Gazette* together with a notice intimating that t is proposed to issue such regulations as regulations under this section within a stated period, but not less than 4 [four] weeks as from the date of the said publication, and inviting interested persons to submit any objections to or representations concerning the proposed regulations: Provided that, if the Minister thereafter determines on any alterations in the regulations published as aforesaid, as a result of any objections or representations submitted thereafter, it shall not he necessary to publish such alterations. before finally issuing the regulations in terms of subsection (1). **(5)** Any regulation involving financial matters shall be made in consultation with the Minister of Finance."'

No. and year of Law	Short title	Extent of Amendment
		The substitution of section 26 of Act 36 of 1947 **18. The following section is hereby substituted for section 26 of Act 36 of 1947:** **"26. This Act shall be called the Fertilizers. Farm Feeds and agricultural Remedies Act, 1947.".**
		Substitution of long title of Act 36 of 1947 as amended by section 3 of Act 48 of 1950, section 44 of Act 28 of 1961, and substituted by section 16 of Act 60 of 1970, section 22 of Act 24 of 1977 and section 10 of Act 4 of 1980 **19. The following long title is hereby substituted for the long tide of Act 36 of 1947:** "To provide for the appointment of a Registrar of Fertilizers, Farm Feeds and Agricultural Remedies: for the registration of fertilizers, farm feeds, agricultural remedies, sterilizing plants and pest control operators; to regulate or prohibi tbe importation, sale, acquisition, disposal or use of fertilizers, farm feeds and agricultural remedies; to provide for the designation of technical advisers and analysts; and to provide for matters incidental thereto.".

MEMORANDUM ON THE OBJECTS OF THE SOUTH AFRICAN MEDICINES AND MEDICAL DEVICES REGULATORY AUTHORITY BILL, 1998

1. PURPOSE OF BILL

The regulation and registration system for medicines for human and animal use and for medical devices established by the Medicines and Related Substances Control Act, 1965 (Act No 101 of 1965), is unable to meet the challenges which currently face a medicines regulatory system. In order to address the defects of the old system, it is considered imperative that new legislation be enacted.

The South African Medicines and Medical Devices Regulatory Authority Bill, 1998 (hereafter "the Bill") seeks to deal with the deficiencies of the system established in 1965 through the establishment of an independent Medicines Regulatory Authority, the South African Medicines and Medical Devices '<regulatory Authority (hereafter "the Authority"), which will replace the Medicines C ntrol Council.

The Authority is a juristic person and is granted e emption from the payment of income tax, stamp duty, levies or fees which would otherwise have been payable by the Authority in terms of any law. The Bill protect: members of the Authority, its committees, persons co-opted to such committees and persons contracted by the Authority to assist in the performance of the Authority's functions in terms of the Bill, from legal proceedings resulting from any acts they perform in good faith for the Authority.

In order to ensure that employees of the Department of Health and the Department of Agriculture who have been responsible for the regulation of medicines and veterinary medicines continue to serve the cause of medicines regulation, the Bill provides for their transfer to the Authority without any loss in respect to their benefits.

The primary object of the Authority is to attend to the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, complementary medicines, veterinary medicines, medical devices, clinical trials and other related matters.

The Authority will have sole responsibility for the technical evaluation, regulation and registration of medicines and medical devices. To this end, the Authority has a duty to appoint standing technical committees consisting of experts and persons with skills and experiences in the area of medicines and medical devices.

The Minister has responsibility for setting out policy concerning the objects of the Authority. There is however, a duty on the Minister to consult the Authority before issuing policy. In order to obtain the views of any other interested person regarding the policy the Minister intends to issue, the Minister also has a duty to cause the text of such policy to be published in the *Gazette* and to invite the lodging of representations thereon. The Bill also provides for steps which the Minister may take in the event of the Authority not complying with the Bill.

The management of the Authority shall be the responsibility of a Board appointed by the Minister for that purpose.

The Bill addresses the confusion that has hitherto existed in respect to the regulation of veterinary medicines by removing stock remedies from regulation in terms of the Farm Feeds, Fertilizers, Agricultural Remedies and Stock Remedies Act, 1947 (Act No 36 of 1947), Veterinary medicines, like other medicines, will now be regulated by the Authority.

The Bill also gives long overdue attention to the proper recognition and regulation of complementary medicines. As the disciplines of orthodox and complementary medicines are in many ways different, the Bill makes provision for the determination

of different processes or guidelines for the evaluation of orthodox medicines, complementary medicines, veterinary medicines or devices or any class or category thereof.

In order to ensure that the integrity of the medicines and medical devices regulatory process is not undermined by any conflicts of interestson the part of those entrusted with this responsibility, the Bill prohibits a member of the Authority and any other person contracted to render a service to the Authority, from amongst other things, voting at or attending proceedings of the Authority dealing with a matter in which he or she has an interest.

The Bill repeals the Medicines and Related Substances Control Act, 1965 and all other laws dealing with medicines regulation which formed part of the legislation of the former Republics of Transkei, Bophuthatswana, Venda and Ciskei and those laws dealing with medicines regulation which formed part of the legislation of the National States of Lebowa, Gazankulu, Qwaqwa, KwaZulu, KwaNdebele and KaNgwane in terms of the Self-governing Territories Constitution Act, 1971 (Act No 21 of 1971).

The Bill provides for the continuation of Regulations and Schedules of substances which in terms of the Medicines and Related Substances Act, 1965 had been in existence, subject to their consistency with the Bill and any repeal or amendment of them by a competent authority.

The Bill binds the State.

2. **CONTENT OF BILL**

2.1 **Introductory Provisions**

Chapter I sets out the definitions to this Bill.

2.2 **South African Medicines and Medical Devices Regulatory Authority**

Chapter II provides for the establishment of the Authority (clause 2). Clauses 3 and 4 deal with the vesting of certain rights and obligations to the Authority as well as the vesting of certain State property in the Authority. Clause 5 sets out the objects and functions of the Authority. Clauses 6, 7, 8, 9, 10, 11, 12 and 13 deal with the constitution of the Board of the Authority, qualifications of members of the Board, disqualification of members of the Board, removal of a Board member from office, vacancies in the Board, meetings of the Board, remuneration and allowances of members of the Board.

Clause 14 deals with the disclosure of conflicting interests. Clause 15 provides that proceedings of the Authority are not invalid in certain circumstances. Clause 16 makes provision for the staff of the Authority. Clause 17, 18, 19 and 20 deal with the financing of the Authority, the raising of loans by the Authority, finances of the Authority and the operation of a banking account by the Authority.

2.3 **Committees and Appointment of Experts**

Chapter 111 provides for the establishment of committees of the Authority (clause 2 I); the remuneration and allowances payable to committee members (clause 22); and the appointment of experts (clause 23).

2.4 **Registration of Medicines and Devices; Prohibition of the Manufacture and Sale of Medicines and Devices which are subject to Registration and are not Registered; Appeal against decisions of the Authority; Furnishing of Information to the Authority regarding Medicines and Devices**

Chapter IV provides for the registration of medicines and devices (clause 24); the prohibition of the manufacture, packaging, distribution, marketing and sale of medicines and devices which are subject to registration and are not registered (clause 25); appeal against decisions of the Authority (clause 26); and the furnishing of information regarding medicines and devices to the Authority (clause 27).

2.5 Measures to Control **Labels** and Advertising; **Sale of** Unregistered Medicines and Devices; and the **Control** of Medicines and Devices

Chapter V provides for measures to control labels and advertising (clause 28); the publication or distribution of false advertisements concerning medicines and devices (clause *29).* Clause 30 provides for the authorisation by the Authority of the sale of unregistered medicines and devices for certain purposes. Clause 31 provides for the control of medicines, Scheduled substances and devices and clause 32 provides for the exclusion of certain medicines from the operation of the Bill. Clauses 33, 34, and 35 provide for licensing, the period of validity and renewal of a licence, and the suspension and/or cancellation of a licence.

Clause 36 provides for the disposal of undesirable medicines and devices. Clause 37 makes provision for analysts, pharmacologists and pathologists. Clause 38 makes provision for the delegation of powers and Clause 39 provides for the vicarious liability of employers for the unlawful acts of their managers, agents or employees.

2.6 **Inspectorate**

Chapter VI makes provision for the designation of certain members of the Authority as inspectors, to ensure the proper enforcement of the provisions of this Bill, as well as their power to enter and search premises and seize articles or documents on the authority of a warrant (clause 40). Clauses 41, 42, and 43 set out a number of offences in terms of the Bill. penalties for such offences, and provides for dealing with certain presumptions and evidence.

2.7 **Winding up of Authority; Prohibition of Disclosure of Certain Information; Regulations; Repeal of Act 101 of 1965 and other Acts as well as the Amendment of Certain provisions of Act 36 of 1947; the Continuation of Regulations and Schedules determined in terms Act 101 of 1965**

Chapter VII provides for the winding up of the Authority (clause 44); the prohibition of the disclosure of certain information (clause 45); proceedings by Minister in case of non-compliance with the Bill by the Authority (clause 46); limitation of liability (clause 47); the making of Regulations (clause 48); the binding of Act on the State (clause 49); the repeal and amendment of certain sections and savings (clause 50); the repeal of certain laws clause 51); the operation of Act in relation to other laws (clause 52); the continuation of Regulations and Schedules of substances determined in terms of Act 101 of 1965 (clause 53); and the amendment of Schedules of substances (clause 54).

Clause 55 provides for the short title of the Bill and the date of commencement.

3. **PARTIES CONSULTED**

Department of Finance:
Department of Public Service and Administration;
Department Agriculture;
The Medicines Regulatory Authority Task Team appointed by the Minister of Health; and the
Medicines Control Council established in terms of Act 101 of 1965.

4. **PARLIAMENTARY PROCEDURE**

The Department of Health and the State Law Advisers are of the opinion that the Bill must be dealt with by Parliament in accordance with the procedure established by section 75 of the Constitution of the Republic of South Africa, 1996 (Act No 108 of 1996).