REPUBLIC OF SOUTH AFRICA

GOVERNMENT GAZETTE

STAATSKOERANT

VAN DIE REPUBLIEK VAN SUID-AFRIKA

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No. 19615

OFFICE OF THE PRESIDENT

'o. 1634. 18 December 1998

It is hereby notified that the President has assented to the ollowing Act which is hereby published for general ıformation:—

'o. 132 of 1998: South African Medicines and Medical Devices Regulatory Authority Act, 1998.

KANTOOR VAN DIE PRESIDENT

No. 1634. 18 Desember 1998

Hierby word bekend gemaak dat die President sy goedkeuring geheg het aan die onderstaande Wet wat hierby ter algemene inligting gepubliseer word:—

No. 132 van 1998: Wet op die Suid-Afrikaanse Medisyne en Mediese Toestelle Regulerende Owerheid, 1998.

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 enactments.

(English text signed by the President.)
(Assented to 11 December 1998.)

ACT

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:—

ARRANGEMENT OF SECTIONS

CHAPTER I

INTRODUCTORY PROVISIONS

Section

CHAPTER II

SOUTH AFRICAN MEDICINES AND MEDICAL DEVICES REGULATORY AUTHORITY

ALGEMENE VERDUIDELIKENDE NOTA:

[ ] Woorde in vet druk tussen vierkantige hake dui skrappings uit bestaande verordenings aan.

Woorde met 'n volstreep daaronder, dui invoegings in bestaande verordenings aan.

(Engelse teks deur die President geteken.)
(Goedgekeur op 11 Desember 1998.)

WET

Om voorsiening te maak vir die regulering en registrasie van medisyne bedoel vir menslike en vir dierlike gebruik; vir die regulering en registrasie van mediese toestelle; vir die instelling van die Suid-Afrikaanse Regulerende Owerheid vir Medisyne en Mediese Toestelle; vir die beheer van ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, gelyste stowwe en mediese toestelle; vir die beheer van persone wat ortodokse medisyne, komplementêre medisyne en veterinêre medisyne mag toeberei en resepteer; vir die herroeping van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965; vir die wysiging van die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947; en vir aangeleenthede wat daarmee in verband staan.

DAAR WORD BEPAAL deur die Parlement van die Republiek van Suid-Afrika, soos volg:—

INDELING VAN ARTIKELS

HOOFSTUK I

INLEIDENDE BEPALINGS

Artikel

HOOFSTUK II

SUID-AFRIKAANSE REGULERENDE OWERHEID VIR MEDISYNE EN MEDIESE TOESTELLE

CHAPTER VI

INSPECTORATE

CHAPTER VII

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

SCHEDULE

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 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;

HOOFSTUK VI

INSPEKTORAAT

HOOFSTUK VII

ONTBINDING VAN OWERHEID, VERBOD OP OPENBAARMAKING VAN SEKERE INLIGTING, REGULASIES, HERROEPING EN WYSIGING VAN SEKERE ARTIKELS VAN WET 101 VAN 1965 EN WET 36 VAN 1947, EN VOORBEHOUDSBEPALINGS

BYLAE

HOOFSTUK I

INLEIDENDE BEPALINGS

Woordomskrywing

1. In hierdie Wet, tensy dit uit die samehang anders blyk, beteken—

"advertensie", met betrekking tot enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, mediese toestel of gelyste stof, enige skriftelike, geïllustreerde, visuele of ander beskrywende stof of mondelinge stelling of verwysing—

(a) wat in enige koerant, tydskrif, pamflet of ander publikasie verskyn; of

(b) wat aan lede van die publiek versprei word; of

(c) wat op enige wyse hoegenaamd onder die aandag van die publiek gebring word, wat bedoel is om die verkoop van daardie ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, mediese toestel of geskedu-leerde stof te bevorder, en het "adverteer" 'n ooreenstemmende betekenis;

"Appèlraad" die Appèlraad aangestel ingevolge artikel 26(1);

"apteker" 'n persoon wat as sodanig geregistreer is kragtens die Wet op Aptekers, 1974;

"apteker-intern" 'n persoon wat as sodanig geregistreer is kragtens die Wet op Aptekers, 1974 (Wet No. 53 van 1974);

"aptekersondersteuningspersoneel" die verskillende kategorieë onder-steuningspersoneel soos voorgeskryf en wat as sodanig geregistreer is kragtens die Wet op Aptekers, 1974, en ook 'n aptekersassistent wat kragtens die Wet geregistreer is;

"dag" 'n kalenderdag;

"Departement" die Departement van Gesondheid of, met betrekking tot enige aangeleentheid rakende veterinêre medisyne, die Departement van Gesondheid en die Departement van Landbou;

"Direkteur-generaal" die Direkteur-generaal: Gesondheid of, met betrekking tot

"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

enige aangeleentheid rakende veterinêre medisyne, die Direkteur-generaal: Gesondheid handelende in oorleg met die Direkteur-generaal: Landbou;

"etiket" enige kenmerk of merk of enige skriftelike, geïllustreerde of ander beskrywende stof wat verskyn op of geheg is aan of verpak is met en betrekking het op enige artikel of die pakket wat enige artikel bevat; en "etiketteer" van 'n kenmerk of merk voorsien of op 'n ander wyse onderskei of beskryf;

"farmakon-wakkerheid" die aktiewe versameling, opsporing, beoordeling en voorkoming van ongewenste geneesmiddeleffekte;

"gade" ook 'n persoon wat saam met iemand woon asof hulle getroud is of saam met wie iemand gewoonlik woon;

"gelyste stof" enige medisyne of ander stof kragtens artikel 32 voorgeskryf;

"goedgekeurde naam", met betrekking tot 'n medisyne, die internasionale nie-handelsnaam (INN) van sodanige medisyne of, waar daar nie so 'n naam bestaan nie, sodanige ander naam as wat die Raad bepaal wat nie 'n fabrikaat of handelsnaam is wat kragtens die Wet op Handelsmerke, 1993 (Wet No. 194 van 1993), geregistreer is nie;

"Grondwet" die Grondwet van die Republiek van Suid-Afrika, 1996 (Wet No. 108 van 1996);

"hierdie Wet" ook die regulasies;

"Hoof- Uitvoerende Beampte" die Hoof- Uitvoerende Beampte aangestel ingevolge artikel 16(2);

"hospitaal" enige instelling ingestel as 'n hospitaal of 'n verpleeginrigting of as sodanig geregistreer ingevolge enige wet;

"inspekteur" 'n persoon as sodanig aangewys kragtens artikel 40;

"komplementêre medisyne" enige stof of mengsel van stowwe—

(a) wat van plantaardige, minerale, of dierlike oorsprong is, en wat geklassifiseer kan word, maar nie daartoe beperk is nie, as kruie, homeopaties, ayurvedies of voedingkundig; en

(b) wat gebruik word of bedoel is om gebruik te word vir of vervaardig of verkoop word vir gebruik, of bedoel is om nuttig te wees ter aanvulling van die genesende krag van 'n menslike of dierlike liggaam, of waarvoor daar 'n aanspraak is met betrekking tot sy uitwerking ter aanvulling van die genesende krag van 'n menslike of dierlike liggaam in die behandeling, verandering, verligting of voorkoming van siekte, abnormale ligaamlike of geestelike toestand of die simptome daarvan by 'n mens of 'n dier; en

(c) wat gebruik word, maar nie daartoe beperk nie, in die dissiplines van Westerse kruie-, tradisionele Afrika-, tradisionele Chinese-, Homeopatiese, Ayurvediese, Unani, Antroposofiese, Aromatiese terapie en Voedselaanvulling; of

(d) wat weens sy oorsprong, beoogde gebruik of gebruik in 'n dissipline deur die Owerheid, by kennisgewing in die *Staatskoerant*, as 'n komplementêre medisyne bepaal is;

"mediese praktisyn" 'n persoon wat as sodanig geregistreer is kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974) en ook 'n intern wat kragtens daardie Wet geregistreer is;

"mediese toestel" of "toestel" enige instrument, werktuig, materiaal, masjien, apparaat, implantaat of diagnostiese reagens of enige ander artikel, hetsy dit alleen of in kombinasie gebruik word, insluitende sagteware wat vir die behoorlike aanwending daarvan nodig is wat gebruik word vir of wat heet geskik te wees vir gebruik of vervaardig of verkoop vir gebruik deur mense by—

(i) die diagnose, voorkoming, monitering, behandeling of verligting van siekte; of

(ii) die diagnose, monitering, behandeling of verligting van of vergoeding vir 'n besering of gebrek; of

(iii) die ondersoek, vervanging of modifikasie van die anatomie of van 'n fisiologiese proses; of

(iv) die diagnose van swangerskap, of die beheer van bevrugting of die beëindiging van swangerskap;

en wat sy vernaamste bedoelde werking in of op die menslike liggaam nie op chemiese, farmakologiese, immunologiese of metaboliese wyse bereik nie, maar wat in sy funksie deur sodanige middele aangehelp kan word;

(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 to, 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 as 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;

"Medisynewet" die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (Wet No. 101 van 1965);

"Minister" die Minister van Gesondheid of, met betrekking tot 'n aangeleentheid rakende veterinêre medisyne, die Minister van Gesondheid handelende in oorleg met die Minister van Landbou;

"ongewenste effekte of ongewenste geneesmiddeleffekte" die onbedoelde nadelige uitwerking van 'n medisyne wanneer dit in sy normale dosis gebruik word;

"onmiddellike familielid", met betrekking tot 'n persoon, daardie persoon se gade, ouer, kind, broer of suster;

"onmiddellike houer", met betrekking tot 'n ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stof, 'n houer wat in regstreekse aanraking met die medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stof is;

"ontleder" 'n ontleder aan wie gesag kragtens artikel 37 verleen is;

"ortodokse medisyne" enige stof of mengsel van stowwe wat bedoel is om gebruik te word deur, of toegedien word aan, mense vir enige van die volgende terapeutiese doeleindes:

(a) behandeling, voorkoming of verligting van siektesimptome, abnormale liggaamlike of geestelike toestand of die simptome daarvan;

(b) diagnosering van siekte of die vasstelling van die bestaan, graad of omvang van 'n fisiologiese toestand;

(c) andersins ter voorkoming of ingryping van die normale werking van die fisiologiese funksie, hetsy permanent of tydelik en hetsy deur middel van beëindiging, verlaging, uitstel of verhoging of versnelling van die werking van daardie funksie;

"Ouditeur-generaal" die persoon wat ingevolge item 20 van Bylae 6 van die Grondwet voortgaan om te funksioneer en die amp te beklee ingevolge die Wet op die Ouditeur-generaal, 1995 (Wet No. 12 van 1995), of as sodanig aangestel is ingevolge artikel 193 van die Grondwet;

"ouditkomitee" die ouditkomitee aangestel ingevolge artikel 19(3);

"Owerheid" die Suid-Afrikaanse Regulerende Owerheid vir Medisyne en Mediese Toestelle ingestel by artikel 2;

"patoloog" 'n patoloog aan wie gesag verleen is kragtens artikel 37;

"praktisyn" 'n persoon wat as sodanig geregistreer is kragtens die Wet op Chiropraktisyns, Homeopate en Verwante Gesondheidsdiensberoepe, 1982 (Wet No. 63 van 1982);

"Raad" die Raad aangestel ingevolge artikel 6(1);

"register", die register bedoel in artikel 24, en "registreer", in die register aanteken;

"regulasie" 'n regulasie kragtens hierdie Wet uitgevaardig;

"tandarts" 'n persoon wat as sodanig geregistreer is ingevolge die Wet op Gesondheidsberoepe, 1974;

"toebereiding" die interpretasie en evaluering van 'n voorskrif, die uitkies, manipulasie van medisyne, die etiketteer en verskaffing van medisyne in 'n paslike houer aan, en die voorsiening van inligting en instruksies om die veilige en doeltreffende gebruik van 'n medisyne deur, 'n pasiënt, en "toeberei" het 'n ooreenstemmende betekenis;

"uitvoer" ook lewering of verskaffing binne die Republiek vir versending na enige bestemming buite die Republiek;

"veearts" 'n persoon wat ingevolge die Wet op Veterinêre en Para-Veterinêre Beroepe, 1982 (Wet No. 39 van 1982), geregistreer is of geag word aldus geregistreer te wees;

"veemiddel" enige stof of mengsel van stowwe wat kragtens die Wet op Veemiddels geregistreer is;

"Veemiddelswet" die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947 (Wet No. 36 van 1947).

"verkoop" by die groot of klein maat verkoop en ook vir verkoop invoer, aanbied, adverteer, hou, versend, stuur, vervoer of lewer, of 'n verkoop magtig, gelas of toelaat, of vir verkoop berei of besit en ook ruil of verskaf of van die hand sit aan enigiemand hetsy teen 'n teenprestasie of andersins, en het "verkoop" as 'n selfstandige naamwoord 'n ooreenstemmende betekenis;

"Stock Remedies Act", means the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No 36 of 1947);

"this Act" includes the regulations;

"veterinarian" means a person registered or deemed to be registered under the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 39 of 1982);

"veterinary medicine" means any substance or mixture of substances intended or manufactured for use in connection with animals 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 may be 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

"verpleegkundige" 'n persoon as verpleegkundige kragtens die Wet op Verpleging, 1978 (Wet No. 50 van 1978), geregistreer;

"verpakking" enigiets waarin of waardeur enige medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stof ingesluit, bedek, vervat of verpak is;

"vervaardiging" alle bedrywighede met inbegrip van die aankoop van materiaal, verwerking, produsering, verpakking, kwaliteitskontrole, vrystelling en stoor van geneeskundige produkte en verbandhoudende beheer;

"vervangbare multibronmedisyne" medisyne wat dieselfde aktiewe stowwe bevat wat identies is in sterkte of konsentrasie, dosisvorm en roete van toediening en aan dieselfde of vergelykbare standaarde voldoen, wat voldoen aan die vereistes vir terapeutiese gelykwaardigheid soos voorgeskryf;

"veterinêre medisyne" enige stof of mengsel van stowwe bedoel of vervaardig vir gebruik in verband met diere vir die diagnose, behandeling, verligting, modifikasie of voorkoming van siekte of ongesonde liggaamlike toestand, vir die verbetering van groei, produksie of werkvermoë, vir die houvermoë van karkasse, vir die genesing, regstelling of verandering van gedrag of vir genadedood op menslike wyse, maar nie ook veevoer nie;

"voorskryf" by regulasie voorskryf.

HOOFSTUK II

SUID-AFRIKAANSE REGULERENDE OWERHEID VIR MEDISYNE EN MEDIESE TOESTELLE

Instelling van Suid-Afrikaanse Regulerende Owerheid vir Medisyne en Mediese Toestelle

2. (1) Die Suid-Afrikaanse Regulerende Owerheid vir Medisyne en Mediese Toestelle word hierby ingestel.

(2) Die Owerheid is 'n regspersoon.

(3) Die Owerheid moet onafhanklik en onpartydig wees by die verrigting van sy funksies.

(4) *(a)* Die Minister kan by kennisgewing in die *Staatskoerant* beleid uitvaardig in ooreenstemming met die oogmerke in artikel 5 bedoel.

(b) Die Minister moet, alvorens beleid in paragraaf *(a)* beoog uitgevaardig word—

(i) met die Owerheid oorleg pleeg;

(ii) ten einde die mening van belanghebbende persone in te win, die teks van sodanige beleid in die *Staatskoerant* laat publiseer tesame met 'n kennisgewing waarin die Minister se voorneme om daardie beleid uit te vaardig gestel word en belanghebbende persone versoek word om skriftelike vertoë met betrekking tot die beleid op die wyse in sodanige kennisgewing vermeld, in te dien binne 30 dae na die datum van sodanige kennisgewing of sodanige ander tydperk as wat die Minister bepaal.

(c) Paragraaf *(b)* is nie van toepassing nie ten opsigte van enige wysiging deur die Minister van 'n beleid as gevolg van kommentaar of vertoë wat die Minister ontvang na aanleiding van oorleg of publikasie ingevolge daardie paragraaf.

(d) 'n Beleid uitgevaardig kragtens hierdie artikel kan deur die Minister gewysig, ingetrek of vervang word, en hierdie artikel is van toepassing, met die nodige veranderinge wat die konteks vereis, met betrekking tot enige sodanige wysiging, intrekking of vervanging.

(5) Die bestuur van die sake van die Owerheid word deur die Raad behartig.

(6) Die Raad bestuur die sake van die Owerheid in ooreenstemming met die beleid deur die Minister bepaal.

(7) Die Owerheid verrig sy funksies ingevolge hierdie Wet.

(8) Die Raad kan, en moet op versoek van die Minister, die Minister van advies dien oor enige aangeleentheid wat deur hierdie Wet gedek word.

Oorgang van sekere regte en verpligtinge ten opsigte van eiendom op die Owerheid

3. Al die regte en verpligtinge van die Staat en van die Medisynebeheerraad ten opsigte van al die roerende eiendom wat onmiddellik voor die inwerkingtreding van

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 for 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 and 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 must 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 person appointed 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.

hierdie Wet gebruik is uitsluitlik in verband met die werk wat deur die beamptes en werknemers van die Staat vir doeleindes van die funksies van die Medisynebeheerraad en, in die geval van veemiddels, die Registrateur van Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, verrig is, gaan sonder enige aanspreeklikheid om vergoeding te betaal, oor op die Owerheid.

Oorgang van sekere Staatseiendom op die Owerheid

4. Alle roerende Staatseiendom wat onmiddellik voor die inwerkingtreding van hierdie Wet gebruik is uitsluitlik vir die doeleindes en funksies van die Medisynebeheerraad, die Direktoraat Medisyneadministrasie en, in die geval van veemiddels, die Registrateur van Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, gaan sonder enige aanspreeklikheid om vergoeding te betaal, oor op die Owerheid.

Oogmerke en funksies van Suid-Afrikaanse Regulerende Owerheid vir Medisyne en Mediese Toestelle

5. Die primêre oogmerk van die Suid-Afrikaanse Regulerende Owerheid vir Medisyne en Mediese Toestelle is, behoudens die bepalings van hierdie Wet, om voorsiening te maak vir die monitering, evaluering, regulering, ondersoek, inspeksie, registrasie en beheer van medisyne, komplementêre medisyne, veterinêre medisyne, kliniese toetse en mediese toestelle en verwante aangeleenthede in openbare belang, en vir daardie doel moet hy—

(a) die doeltreffende, doelmatige en etiese evaluering en registrasie verseker van medisyne, komplementêre medisyne, veterinêre medisyne en toestelle wat voldoen aan omskrewe standaarde van gehalte, veiligheid en doeltreffendheid;

(b) verseker dat die proses van die evaluering en registrasie van medisyne, komplementêre medisyne, veterinêre medisyne en toestelle deursigtig, billik en objektief is en betyds afgehandel word, behoudens hierdie Wet;

(c) die periodieke herevaluering en monitering van medisyne, komplementêre medisyne, veterinêre medisyne en toestelle verseker;

(d) verseker dat bewyse van bestaande en nuwe ongewenste geneesmiddeleffekte, wisselwerkings en inligting oor farmakowaaksaamheid globaal gemoniteer en ontleed word en tot optrede lei;

(e) verseker dat die nakoming van bestaande wetgewing en regulasies bevorder en beheer word deur 'n proses van daadwerklike inspeksie en ondersoek; en

(f) verseker dat kliniese toetsprotokolle geëvalueer word volgens voorgeskrewe etiese en professionele maatstawwe en omskrewe standaarde.

Samestelling van Raad

6. (1) Die Minister moet binne 60 dae na die datum van inwerkingtreding van hierdie Wet 'n Raad aanstel wat bestaan uit—

(a) 'n voorsitter aangestel deur die Minister;

(b) 'n ondervoorsitter aangestel deur die Minister;

(c) 'n persoon wat die Minister van Landbou verteenwoordig, aangestel deur die Minister;

(d) 'n persoon wat die Minister verteenwoordig, aangestel deur die Minister; en

(e) ten minste vyf maar hoogstens elf ander persone, soos wat die Minister bepaal.

(2) Die Raad moet, in oorleg met die Minister, 'n Uitvoerende Komitee uit sy lede aanstel, bestaande uit die voorsitter, die ondervoorsitter en hoogstens drie ander lede, van wie een die lid van die Raad moet wees wat die Minister van Landbou verteenwoordig.

(3) Die Minister moet bepaal of 'n persoon wat in die Raad aangestel word, in 'n voltydse of deeltydse hoedanigheid moet dien.

(4) Die Hoof- Uitvoerende Beampte en voorsitters van Staande Komitees wat deur die Raad aangestel is, is *ex officio* lede van die Raad sonder stemreg.

(5) Alle handelinge van die Raad word as die handelinge van die Owerheid beskou.

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 on 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 cross-section of the population of the Republic.

Disqualification of members of Board

8. (1) A person may not be appointed or continue as 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 1978), 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 person 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 not 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 to serve in a full-time capacity, serves in such capacity to the exclusion of any other remunerative employment, occupation or office.

Kwalifikasies van lede van Raad

7. Lede van die Raad moet behoorlik gekwalifiseerde, gepaste en geskikte persone wees wat—

(a) verbind is tot—

(i) die oogmerke van hierdie Wet; en

(ii) billikheid, openlikheid en aanspreeklikheid aan die kant van diegene aan wie die taak opgedra is om aan die publiek toegang tot medisyne, komplementêre medisyne, veterinêre medisyne en toestelle te verleen; en

(b) gesamentlik 'n breë deursnee van die bevolking van die Republiek uitmaak.

Diskwalifikasie van lede van Raad

8. (1) 'n Persoon mag nie as lid van die Raad aangestel word of aanbly nie indien daardie persoon —

(a) nie 'n Suid-Afrikaanse burger is nie;

(b) nie permanent in die Republiek woonagtig is nie;

(c) ingevolge die Wet op Veterinêre en Para-veterinêre Beroepe, 1982 (Wet No. 19 van 1982), die Wet op Chiropraktisyns, Homeopate en Verwante Gesondheidsdiensberoepe, 1982 (Wet No. 63 van 1982), die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), die Wet op Aptekers, 1974 (Wet No. 53 van 1974), of die Wet op Verpleging, 1978 (Wet No. 50 van 1978), of enige ander beroepsliggaam, gediskwalifiseer is om daardie persoon se beroep te beoefen, terwyl hy of sy aldus gediskwalifiseer is;

(d) in diens is van of die belange verteenwoordig van die medisyne-, komplementêre medisyne-, veterinêre medisyne- of toestelnywerheid;

(e) 'n gekose lid van die Parlement, 'n provinsiale wetgewer of 'n plaaslike regering is;

(f) of 'n onmiddellike familielid van sodanige persoon 'n beherende belang of enige wesenlike finansiële belang in die medisyne-, komplementêre medisyne-, veterinêre medisyne- of toestellenywerheid het;

(g) of die sakevennoot van daardie persoon 'n amp beklee in of by of in diens is van enige persoon, maatskappy, organisasie of ander liggaam, hetsy ingelyf al dan nie, wat 'n belang het soos in paragraaf *(f)* beoog;

(h) 'n ongerehabiliteerde insolvent is;

(i) deur 'n bevoegde hof as geestesongesteld verklaar is soos omskryf in die Wet op Geestesgesondheid, 1973 (Wet No. 18 van 1973);

(j) te eniger tyd, hetsy binne die Republiek of elders, skuldig bevind is aan—

(i) diefstal, bedrog, vervalsing of die in omloop bring van 'n vervalste dokument, meineed, 'n misdryf ingevolge die Wet op Korrupsie, 1992 (Wet No. 94 van 1992), of enige ander misdryf waarby oneerlikheid betrokke is;

(ii) enige misdryf wat wesenlik ooreenstem met enige misdryf in subparagraaf (i) bedoel.

(2) 'n Persoon wat onderworpe was aan 'n diskwalifikasie beoog in subartikel (1)*(a)* tot *(i)* kan as 'n lid van die Raad aangestel word indien daardie persoon ten tyde van sodanige aanstelling nie meer aan daardie diskwalifikasie onderworpe is nie.

Ampstermyne van lede van Raad

9. (1) 'n Lid van die Raad beklee die amp vir 'n termyn van hoogstens vyf jaar, en kan heraangestel word vir nog een termyn van hoogstens vyf jaar.

(2) 'n Lid van die Raad kan te eniger tyd uit die Raad bedank met ten minste drie maande skriftelike kennis aan die Minister of sodanige korter kennistyd as wat die Minister magtig.

(3) Ondanks subartikel (1) kan 'n lid van die Raad, met die magtiging van die Minister, in die amp aanbly na voltooiing van daardie lid se ampstermyn tot met die begin van die ampstermyn van daardie lid se opvolger, maar sodanige verlengde ampstermyn mag nie langer as 45 dae wees nie.

(4) 'n Lid van die Raad wat aangestel is om in 'n voltydse hoedanigheid te dien, moet in sodanige hoedanigheid dien tot uitsluiting van enige ander besoldigde diens, beroep of amp.

(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)*(a)* 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 chairperson 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.

(5) Ondanks subartikel (4) kan die Minister, op sodanige bedinge en voorwaardes as wat hy of sy bepaal, 'n lid wat aangestel is om in 'n voltydse hoedanigheid te dien, toelaat om 'n ander besoldigde diens, beroep of amp te hou.

Ontheffing van amp

10. Ondanks artikel 9 kan 'n lid van die Raad deur die Minister van sy of haar amp onthef word op grond van—

(a) wangedrag, wat moet insluit skending van die Gedragskode wat deur die Raad bepaal en by kennisgewing in die *Staatskoerant* gepubliseer is;

(b) onvermoë om daardie lid se ampspligte doeltreffend te verrig;

(c) afwesigheid van drie opeenvolgende vergaderings van die Raad sonder die toestemming vooraf van die voorsitter, uitgesonderd om goeie redes;

(d) die verrigting deur hom of haar van ander besoldigde werk in stryd met artikel 9(4); of

(e) versuim om 'n belang ingevolge artikel 14(3)*(a)* openbaar te maak of bywoning van of deelname aan verrigtinge van die Raad terwyl hy of sy 'n belang beoog in artikel 14(1) en (2) het.

Vakatures in Raad

11. (1) Daar is 'n vakature in die Raad indien 'n lid—

(a) onderworpe raak aan 'n diskwalifikasie in artikel 8 bedoel;

(b) sy of haar bedanking indien soos beoog in artikel 9(2) en sodanige bedanking van krag word;

(c) van sy of haar amp onthef word ingevolge artikel 10; of

(d) permanent ongeskik raak.

(2) Indien die amp van enige lid vakant raak voor die verstryking van die tydperk waarvoor daardie lid aangestel is, moet die Minister, behoudens artikels 6 en 7, 'n ander persoon aanstel om die amp te beklee vir die onverstreke deel van die tydperk waarvoor daardie persoon se voorganger aangestel is.

Vergaderings van Raad

12. (1) Die Raad moet ten minste agt keer per jaar vergader, en vergaderings moet gehou word op sodanige tye en plekke as wat die Raad bepaal, maar die eerste vergadering moet gehou word op sodanige tyd en plek as wat die voorsitter na oorleg met die Minister bepaal.

(2) In afwesigheid van die voorsitter moet die ondervoorsitter al die funksies van die voorsitter verrig, en in afwesigheid van sowel die voorsitter as die ondervoorsitter moet die oorblywende lede van die Raad uit hulle geledere 'n waarnemende voorsitter kies.

(3) Die voorsitter kan te eniger tyd 'n spesiale vergadering van die Raad belê, wat gehou moet word op sodanige tyd en plek as wat die voorsitter bepaal, maar die voorsitter moet, op versoek van die Minister of indien 'n versoek te dien effekte onderteken deur ten minste drie lede van die Raad aan hom gerig word, 'n spesiale vergadering belê, en indien die voorsitter versuim om 'n spesiale vergadering te belê binne sewe dae na ontvangs van die Minister se versoek of die rig van die versoek deur drie lede van die Raad, kan die lede van die Raad 'n spesiale vergadering belê.

(4) Die kworum vir enige vergadering van die Raad is 'n meerderheid van die lede wat stem.

(5) Behoudens subartikel (4) moet 'n besluit van die Raad geneem word by resolusie aangeneem deur die meerderheid van die lede van die Raad op 'n vergadering van die Raad, en in die geval van 'n staking van stemme oor enige aangeleentheid het die voorsitter 'n beslissende stem benewens die voorsitter se beraadslagende stem.

(6) Die Uitvoerende Komitee kan, behoudens die opdrag van die Raad, al die bevoegdhede en al die funksies van die Raad uitoefen en verrig gedurende tydperke tussen vergaderings van die Raad, maar het nie die bevoegdheid, uitgesonderd in soverre die Raad gelas, om enige besluit van die Raad ter syde te stel of te wysig nie, en enige handeling of besluit van die Uitvoerende Komitee is onderhewig aan bekragtiging op die eerste daaropvolgende vergadering van die Raad.

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 (1), 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 and with the concurrence of the Minister of Finance;

Besoldiging en toelaes van lede van Raad

13. Die voorsitter en ander lede van die Raad, uitgesonderd persone wat in die voltydse diens van die Staat is, moet sodanige besoldiging en toelaes betaal word en is geregtig op sodanige voordele as wat die Minister, na oorleg met die Raad en met die instemming van die Minister van Finansies, bepaal.

Openbaarmaking van botsende belange

14. (1) 'n Lid van die Raad of van die personeel of van enige komitee van die Owerheid, mag nie stem of teenwoordig wees op of op enige ander manier deelneem aan die verrigtinge van enige vergadering of verhoor van die Raad nie of enige komitee van die Owerheid nie, indien—

(a) met betrekking tot 'n aansoek om die registrasie van 'n medisyne, komplementêre medisyne, veterinêre medisyne of toestel, daardie lid of daardie lid se onmiddellike familielid of gade of sakevennoot 'n direkteur, lid of sakevennoot is of 'n belang het in die besigheid van die aansoeker of van enige persoon wat vertoë met betrekking tot die aansoek gerig het;

(b) met betrekking tot enige aangeleentheid voor die Raad, hy of sy enige belang het wat daardie lid belet, of wat vertolk kan word as dat dit daardie lid belet, om daardie lid se funksies as 'n lid van die Owerheid op 'n billike, onpartydige en behoorlike wyse te verrig.

(2) Vir doeleindes van hierdie artikel sluit "belang" in, maar is dit nie beperk nie tot, enige konsultantskap, teen betaling al dan nie, enige navorsingstoekenning waaruit die lid regstreeks of onregstreeks voordeel trek, of enige ekwiteitsbesit of enige uitvoerende of nie-uitvoerende direkteurskap of enige ander betaling of voordeel *in natura*.

(3) Indien daar in enige stadium in die loop van enige verrigtinge van die Raad of 'n komitee van die Owerheid rede is om te vermoed dat 'n lid van die Raad of komitee van die Owerheid 'n belang net soos in subartikel (1) beoog, moet—

(a) daardie lid die aard van sy of haar belang onverwyld openbaar maak en die betrokke vergadering of verhoor verlaat ten einde die oorblywende lede van die Raad of enige komitee van die Owerheid in staat te stel om die aangeleentheid te bespreek en te bepaal of hy of sy op grond van botsende belange belet moet word om aan sodanige verrigtinge deel te neem; en

(b) sodanige openbaarmaking en die besluit geneem deur die oorblywende lede van die Raad of enige komitee van die Owerheid betreffende sodanige bepaling aangeteken word in die notule van die betrokke verrigtinge.

Verrigtinge van die Owerheid in sekere omstandighede nie ongeldig nie

15. 'n Besluit geneem deur die Owerheid, of 'n handeling verrig op gesag van sodanige besluit, is nie bloot omrede—

(a) enige onreëlmatigheid in die aanstelling van 'n lid van die Raad;

(b) die feit dat 'n lid van die Raad skuldig is aan 'n handeling wat sy of haar ampsontheffing regverdig; of

(c) die feit dat enige persoon wat gediskwalifiseer is om 'n lid van die Raad te wees of wat van daardie amp onthef is, as sodanig in die Raad gesit het toe sodanige besluit geneem is,

ongeldig nie indien sodanige besluit geneem is deur 'n meerderheid van die lede van die Raad wat wettiglik geregtig was om te stem en teenwoordig te wees by daardie geleentheid, en bedoelde lede van die Raad by daardie geleentheid 'n kworum gevorm het.

Personeel van Owerheid

16. (1) Die Owerheid moet, in oorleg met die Staatsdienskommissie en behoudens die goedkeuring van die Minister met betrekking tot personeel en hulpbronne, sy eie administrasie instel om sy funksies te verrig.

(2) Die Raad, in oorleg met die Minister, moet, op sodanige bedinge en voorwaardes as wat bepaal word, 'n Hoof- Uitvoerende Beampte aanstel wat die sekretaris van die Raad moet wees en wat—

(i) sodanige besoldiging, toelaes en ander voordele moet ontvang as wat die Raad in oorleg met die Minister en met die instemming van die Minister van Finansies bepaal;

(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 the 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 favourable 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 58 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

(ii) op sodanige bedinge en voorwaardes as wat deur die Raad bepaal word na oorleg met die Staatsdienskommissie en behoudens die goedkeuring van die Direkteur-generaal met betrekking tot hulpbronne, sodanige personeel moet aanstel as wat redelikerwys nodig is om hom of haar by te staan met die werk verbonde aan die verrigting deur die Owerheid van sy funksies;

(iii) behoudens hierdie Wet, verantwoordelik moet wees vir die bestuur van en administratiewe beheer oor die personeel van die Owerheid en vir daardie doel teenoor die Raad rekenpligtig moet wees; en

(iv) die bevoegdhede kan uitoefen en die pligte en funksies moet verrig wat die Raad van tyd tot tyd aan die Hoof- Uitvoerende Beampte verleen of opdra ten einde die oogmerke van die Owerheid te verwesenlik, en vir daardie doel teenoor die Raad rekenpligtig moet wees.

(3) Die Owerheid moet, by die aanstelling van sy personeel—

(a) voorsiening maak vir die vordering van persone wat deur vorige onbillike diskriminasie benadeel is, sodat sy personeel, gesamentlik gesien, 'n breë deursnee van die bevolking van die Republiek verteenwoordig; en

(b) behoudens paragraaf *(a)*, gelykegeleentheid-indiensnemingspraktyke toepas.

(4) Die Owerheid kan aan die persone in sy diens sodanige besoldiging en toelaes betaal en aan hulle sodanige pensioene en ander voordele voorsien as wat die Raad in oorleg met die Minister en met die instemming van die Minister van Finansies en na oorleg met die Staatsdienskommissie bepaal.

(5) Enige beampte of werknemer van die Departement kan deur die Owerheid, in oorleg met die Direkteur-generaal, vir oorplasing na die Owerheid gekies word en moet indien aldus verkies, ondanks enige andersluidende bepaling in die Staatsdienswet, 1994 (Proklamasie No. 103 van 1994), maar behoudens die Wet op Arbeidsverhoudinge, 1995 (Wet No. 66 van 1995), met ingang van die vasgestelde datum of sodanige later datum as waarop daar ooreengekom word tussen die Direkteur-generaal en die Owerheid, ophou om sodanige beampte of werknemer te wees en moet sonder onderbreking van sy of haar diens 'n werknemer van die Owerheid word.

(6) Enige persoon wat aldus oorgeplaas word, moet met ingang van die datum van daardie persoon se oorplasing deur die Owerheid aangestel word op die voorwaardes deur die Owerheid bepaal in 'n pos in die Owerheid wat soortgelyk is aan die pos wat sodanige persoon onmiddellik voor sodanige oorplasing in die Departement beklee het, maar—

(a) sodanige persoon se salaris of salarisskaal mag nie deur sodanige aanstelling verminder word nie;

(b) sodanige persoon behou alle vakansie- en siekteverlof wat onmiddellik voor sy of haar oorplasing tot daardie persoon se krediet staan in die Departement, insluitende alle monetêre voordele daaraan verbonde;

(c) sodanige persoon moet vergoed word vir enige verlies wat daardie persoon ly as gevolg van sodanige oorplasing ten opsigte van werkloosheidbydraes, bydraes vir mediese bystand of ander uitgawes aan gesondheidsorg wat nodig is sodat daardie persoon nie in 'n minder gunstige posisie in dié verband is nie as wat op hom of haar van toepassing was onmiddellik voor daardie persoon se oorplasing, asook vir enige ander verlies voortspruitend uit enige oorplasing van daardie persoon se huidige hoofkwartier na 'n nuwe hoofkwartier in ooreenstemming met die prosedure van toepassing op beamptes en werknemers van die Departement; en

(d) sodanige persoon se diensvoorwaardes ten opsigte van aangeleenthede wat nie in paragrawe *(a)* tot *(c)* van hierdie subartikel vermeld is nie, mag vir daardie persoon nie minder gunstig wees nie as dié wat voor die oorplasing op daardie persoon van toepassing was.

(7) Enige persoon wat ingevolge subartikel (5) van die Departement oorgeplaas word, wat onmiddellik voor sodanige oorplasing 'n lid van die Regeringswerknemers-pensioenfonds was, moet ondanks enige andersluidende bepaling in enige wet of in die reëls van daardie pensioenfonds, by oorplasing 'n lid van daardie pensioenfonds bly vir alle doeleindes, en die Owerheid moet aan gemelde pensioenfonds ten opsigte van daardie persoon bydra in dieselfde mate as wat 'n werkgewer ingevolge die wette oor en die reëls van daardie pensioenfonds moet bydra tot daardie pensioenfonds ten opsigte van 'n werknemer wat 'n lid van daardie fonds is.

(8) Vir doeleindes van die Inkomstebelastingwet, 1962 (Wet No. 58 van 1962), word geen verandering van werkgewer geag plaas te gevind het nie wanneer 'n beampte of werknemer van die Departement ingevolge subartikel (5) na die Owerheid oorgeplaas

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 donations 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.

word, en die posisie van sodanige beampte of werknemer ten opsigte van die infasering van belasting gehef op 'n voordeel of bate wat verkry word as gevolg van diens of die bekleding van 'n amp soos beoog in Bylae 7 van die Inkomstebelastingwet, 1962, word geag onveranderd te bly.

(9) Enige dissiplinêre stappe gedoen of beoog teen enige persoon wat ingevolge subartikel (5) van die Departement oorgeplaas word, ten opsigte van beweerde wangedrag gepleeg voor daardie persoon se oorplasing na die Owerheid, moet afgehandel of gedoen word, na gelang van die geval, ingevolge die wette wat onmiddellik voor sodanige oorplasing op daardie persoon van toepassing was.

(10) Ten minste een maand voor die vasgestelde datum moet die Direkteur-generaal elke beampte en werknemer van die Departement wat vir oorplasing gekies is, skriftelik in kennis stel—

(a) dat daardie persoon ingevolge subartikel (5) vir oorplasing na die Owerheid gekies is en van die pos wat daardie persoon sal beklee en die datum waarop oorplasing sal geskied en dat sodanige oorplasing sal geskied slegs indien daardie persoon daartoe instem; of

(b) indien daardie persoon weier om tot sodanige oorplasing in te stem, en na oorweging van daardie persoon se vertoë, dat daardie persoon se dienste met ingang van 'n bepaalde datum beëindig gaan word as gevolg van die afskaffing van daardie persoon se pos in die Departement; of

(c) dat daardie persoon ingevolge artikel 14 van die Staatsdienswet, 1994, oorgeplaas moet word uit die pos of betrekking wat daardie persoon beklee na enige ander pos of betrekking in daardie persoon se Departement, ongeag of sodanige pos of betrekking in 'n ander afdeling of van 'n laer of hoër gradering of binne of buite die Republiek is.

(11) Enige voorgestelde optrede waarvan 'n beampte of werknemer ingevolge subartikel (10) in kennis gestel word, kan die onderwerp van 'n appèl na die Minister wees.

(12) Enige sodanige appèl moet aanhangig gemaak word binne 14 dae na ontvangs van sodanige kennisgewing deur die beampte of werknemer.

(13) Enige persoon in subartikel (10)*(b)* beoog, is geregtig op spesiale uittreevoorwaardes en -voordele wat vir daardie persoon nie minder gunstig is nie as dié wat ingevolge die Staatsdienswet, 1994, voorgeskryf is ten opsigte van 'n persoon op wie daardie Wet van toepassing is en wie se diens beëindig word op grond van die afskaffing van daardie persoon se pos.

(14) Vir doeleindes van hierdie artikel beteken die term "vasgestelde datum" die datum wat deur die Minister by kennisgewing in die *Staatskoerant* bepaal word.

Finansiering van Owerheid

17. (1) Die bedryfskoste en kapitaalkoste van die Owerheid word gefinansier uit die fondse wat van tyd tot tyd deur die Parlement bewillig word.

(2) Ondanks subartikel (1) kan die fondse van die Owerheid bestaan uit—

(a) sodanige gelde of heffings vir sy dienste as wat voorgeskryf is;

(b) gelde ingesamel, geleen of verkry deur die Owerheid ingevolge artikel 18;

(c) gelde uit enige ander bron verkry.

(3) Die Owerheid kan op die voorgeskrewe wyse skenkings of bydraes van enige persoon ontvang, en moet enige skenkings of bydraes aldus verkry, gebruik vir die doeleindes wat hy bepaal in verband met die verrigting van sy funksies ingevolge hierdie Wet: Met dien verstande dat al sodanige bydraes in die jaarverslag van die Owerheid gepubliseer word.

(4) Die Owerheid kan enige saldo van sy gelde wat aan die einde van 'n boekjaar van die Owerheid oorbly, gebruik vir enige uitgawes in verband met die verrigting van sy funksies ingevolge hierdie Wet.

(5) Die fondse beoog in subartikel (2) vorm nie deel van die Nasionale Inkomstefonds nie.

Lenings

18. (1) Die Owerheid kan, met die goedkeuring van die Minister, verleen na oorleg met die Minister van Finansies, geld insamel of geld leen of verkry van enige persoon of liggaam teen sodanige rentekoers en op sodanige voorwaardes as wat die Minister bepaal.

(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 to 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 this Act may otherwise provide, utilise its assets for the attainment of its objects and matters incidental thereto.

(2) The Authority may establish a reserve fund for such purposes as, with due regard to subsection (1), it may deem fit and must with the approval 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 kept of all the financial transactions, assets and liabilities of the Authority and must for that purpose, and after consultation with the Minister, appoint an audit committee which must consist of the Auditor-General or the Auditor-General's representative and at least one member of the Board.

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

(5) As soon as may be practicable after the completion of every audit the Board must furnish the Minister and the Auditor-General with a annual 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 the Minister must table a copy of the annual report in Parliament within 30 days of receiving 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 information as the Minister may call for from time to time require in respect of the activities or financial position of the Authority.

Banking account

20. The Board must open and maintain in the name 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 by the Authority and from which payments by the Authority or on its behalf must be made.

CHAPTER III

COMMITTEES AND APPOINTMENT OF EXPERTS

Establishment of committees of Authority

21. (1) The Board must, in consultation with the 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, toxicology 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

(2) Behoudens artikel 35 van die Skatkiswet, 1975 (Wet No. 66 van 1975), kan die Minister, met die instemming van die Minister van Finansies, vir die tydperk en op die voorwaardes wat die Minister bepaal, die behoorlike nakoming waarborg deur die Owerheid van enige kontraktuele verpligting aangegaan of aangegaan te word deur die Owerheid teenoor enige party, hetsy binne of buite die Republiek.

Finansies van Owerheid

19. (1) Die Owerheid moet, uitgesonderd in soverre hierdie Wet anders bepaal, sy bates benut vir die bereiking van sy oogmerke en aangeleenthede wat daarmee in verband staan.

(2) Die Owerheid kan 'n reserwefonds instel vir sodanige doeleindes as wat hy goed ag met behoorlike inagneming van subartikel (1), en moet met die goedkeuring van die Minister van Finansies die gedeelte van die gelde in die reserwefonds wat hy nie onmiddellik nodig het nie, op enige wyse belê tot voordeel van die Owerheid.

(3) Die Raad moet behoorlike rekords laat hou van al die finansiële transaksies, bates en verpligtinge van die Owerheid en moet vir daardie doel, en na oorleg met die Minister, 'n ouditkomitee aanstel wat moet bestaan uit die Ouditeur-generaal of die Ouditeur-generaal se verteenwoordiger en ten minste een lid van die Raad.

(4) Die rekeninge van die Owerheid moet jaarliks geouditeer word deur 'n persoon wat as 'n ouditeur geregistreer is ingevolge die Wet op Openbare Rekenmeesters en Ouditeurs, 1991 (Wet No. 80 van 1991), en wat deur die Raad aangestel moet word in oorleg met die Minister en met die instemming van die Ouditeur-generaal.

(5) So gou moontlik na die afhandeling van elke oudit moet die Raad die Minister en die Ouditeur-generaal voorsien van 'n verslag van die oudit, wat sodanige besonderhede bevat as wat voorgeskryf is, tesame met 'n verslag oor die bedrywighede van die Owerheid bevattende die voorgeskrewe besonderhede, en die Minister moet 'n eksempleer van die jaarverslag binne 30 dae na ontvangs daarvan ter tafel lê in die Parlement indien die Paelrment dan in gewone sessie is, maar indien die Parlement nie dan in gewone sessie is nie, binne 30 dae na die begin van die eersvolgende gewone sessie.

(6) Die Raad moet die Minister voorsien van sodanige inligting as wat die Minister van tyd tot tyd verlang ten opsigte van die bedrywighede of finansiële posisie van die Owerheid.

Bankrekening

20. Die Raad moet 'n rekening waarin die gelde wat die Owerheid ontvang, gestort moet word en waaruit betalings deur die Owerheid of ten behoewe van hom gedoen moet word, open en in stand hou op naam van die Owerheid by 'n bank wat ingevolge die Bankwet, 1990 (Wet No. 94 van 1990), as 'n bank geregistreer is.

HOOFSTUK III

KOMITEES EN AANSTELLING VAN KUNDIGES

Instelling van komitees van die Owerheid

21. (1) Die Raad moet in oorleg met die Minister staande komitees instel en hulle voorsitters en ondervoorsitters aanstel, vir, maar nie beperk nie tot—

(a) ortodokse medisyne, wat moet bestaan uit kundiges uit die tersaaklike wetenskaplike dissiplines;

(b) komplementêre medisyne, wat moet bestaan uit persone wat vaardighede of ondervinding in komplementêre medisyne, toksikologie en kliniese farmakologie verteenwoordig;

(c) veterinêre medisyne, wat moet bestaan uit spesiespesialiste en kundiges uit die tersaaklike wetenskaplike dissiplines; en

(d) mediese toestelle, wat moet bestaan uit persone met die spesialiskundigheid wat op hierdie gebied van die regulering van openbare gesondheid vereis word.

(2) Behoudens subartikel (1) kan die Raad sodanige ander komitees instel vir sodanige doeleindes as wat hy nodig ag ten einde hom by te staan met die doeltreffende

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 Authority.

(4) The Board may appoint any appropriately qualified 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 (1), 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. (1) An application for the registration of a medicine, 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 if it is satisfied that the medicine, complementary medicine, veterinary medicine 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 for 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)*

verrigting van sy funksies en kan hy enige sodanige komitee te eniger tyd uitbrei, inkort of ontbind.

(3) Die Hoof- Uitvoerende Beampte moet 'n sekretariaat aanstel wat administratiewe bystand aan die komitees van die Owerheid moet verleen.

(4) Die Raad kan enige geskik gekwalifiseerde persoon wat gepas en geskik is, aanstel in die komitees wat ingevolge hierdie artikel ingestel word.

Besoldiging en toelaes van komiteelede

22. (1) 'n Lid van enige komitee van die Raad wat nie 'n lid van die Raad of op die personeel van die Owerheid is nie, of in die voltydse diens van die Staat is nie, moet die besoldiging en toelaes betaal word wat die Raad van tyd tot tyd in oorleg met die Minister en met die instemming van die Minister van Finansies bepaal.

(2) Vir doeleindes van subartikel (1) kan die Raad 'n onderskeid tref tussen verskillende komitees en verskillende lede daarvan.

Aanstelling van kundiges

23. (1) Die Owerheid kan vir die doel van die verrigting van sy funksies, kundiges aanstel, insluitende kundiges van ander lande.

(2) Die bedinge, voorwaardes, besoldiging en toelaes van toepassing ten opsigte van enige kundige kragtens sy of haar aanstelling moet bepaal word in 'n skriftelike ooreenkoms wat vir daardie doel tussen die Owerheid en die betrokke kundige aangegaan word.

HOOFSTUK IV

Registrasie van medisyne, komplementêre medisyne, veterinêre medisyne en mediese toestelle

24. (1) 'n Aansoek om die registrasie van 'n medisyne, komplementêre medisyne, veterinêre medisyne of toestel moet in die voorgeskrewe vorm aan die Owerheid voorgelê word en moet vergesel gaan van die voorgeskrewe besonderhede en monsters, waar toepaslik, en van die voorgeskrewe registrasiegeld.

(2) Sodra die Owerheid 'n aansoek ontvang het, moet hy—

(a) ontvangs van sodanige aansoek erken en verseker dat indien sodanige aansoek ten opsigte van 'n medisyne of komplementêre medisyne is wat op die lys van noodsaaklike geneesmiddels verskyn of wat nie daarop verskyn nie maar, wat na die mening van die Minister, noodsaaklik is vir nasionale gesondheid, dit onderworpe is aan sodanige prosedures as wat voorgeskryf is ten einde 'n besluit daaroor te bespoedig;

(b) nadat hy 'n ondersoek of navraag oor sodanige medisyne, komplementêre medisyne, veterinêre medisyne of toestel gedoen het en indien hy seker is dat die betrokke medisyne, komplementêre medisyne, veterinêre medisyne of toestel geskik is vir die doel waarvoor dit bedoel is, aan die voorgeskrewe vereistes voldoen en dat die registrasie daarvan in openbare belang is, die registrasie daarvan goedkeur;

(c) indien hy nie seker is dat die betrokke medisyne, komplementêre medisyne, veterinêre medisyne of toestel geskik is vir die doel waarvoor dit bedoel is nie, aan die voorgeskrewe vereistes voldoen nie en dat die registrasie daarvan in openbare belang is nie, die aansoeker skriftelik in kennis laat stel van die redes waarom hy nie seker is nie, en die aansoeker laat inlig dat hy of sy binne 'n tydperk van 60 dae na die datum van kennisgewing die Owerheid kan voorsien van sy of haar kommentaar op die Owerheid se redes waarom hy nie seker is nie;

(d) indien die kommentaar in paragraaf *(c)* bedoel nie binne die tydperk van 60 dae voorgelê word nie, of indien hy na oorweging van die kommentaar wat deur die aansoeker voorgelê is steeds nie seker is nie, die aansoek afkeur.

(3) Vir doeleindes van hierdie artikel beteken "lys noodsaaklike geneesmiddels" die lys van noodsaaklike middels ingesluit in die jongste uitgawe van die amptelike publikasie rakende riglyne vir standaardbehandeling wat deur die Departement saamgestel word.

(4) Vir doeleindes van die ondersoek of navraag in subartikel (2)*(b)* beoog, moet die

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 the 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 holder of a certificate of registration has been invited to make representations 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.

(11) 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

Minister, in oorleg met die Owerheid, verskillende prosesse of riglyne bepaal vir die evaluering van ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestelle of enige klas of kategorie daarvan.

(5) Nadat die Owerheid die registrasie van 'n medisyne, komplementêre medisyne, veterinêre medisyne of toestel goedgekeur het, moet hy dit registreer en sodanige besonderhede met betrekking tot die medisyne, komplementêre medisyne, veterinêre medisyne of toestel aanteken as wat voorgeskryf is om aldus in die register aangeteken te word, en moet hy met betrekking tot daardie medisyne, komplementêre medisyne, veterinêre medisyne of toestel 'n registrasiesertifikaat in die voorgeskrewe vorm aan die aansoeker uitreik.

(6) Die Owerheid moet so gou moontlik nadat 'n medisyne, komplementêre medisyne, veterinêre medisyne of toestel geregistreer is, enigiemand wat hy nodig ag in kennis gestel moet word, in kennis stel en by kennisgewing in die *Staatskoerant*—

(a) die naam en registrasienommer van sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel en die voorwaardes, as daar is, waaraan die registrasie van sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel onderworpe is, publiseer;

(b) die terapeutiese doeltreffendheid van sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel publiseer;

(c) die farmakologiese doel of enige ander doel waarvoor, die omstandighede waaronder en die wyse waarop sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel gebruik moet word, publiseer; en

(d) enige ander aangeleentheid rakende sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel wat na die mening van die Owerheid vir hulle van waarde kan wees, publiseer.

(7) 'n Medisyne, komplementêre medisyne, veterinêre medisyne of toestel wat geregistreer is, insluitende een wat geregistreer is voor die inwerkingtreding van hierdie Wet, kan, behoudens subartikel (10), onderhewig wees aan herregistrasie deur die Owerheid.

(8) 'n Medisyne, komplementêre medisyne, veterinêre medisyne of toestel moet geregistreer word onder sodanige naam as wat die Owerheid goedkeur, en die Owerheid moet aan sodanige geregistreerde medisyne 'n registrasienommer toeken wat vermeld moet word in die registrasiesertifikaat wat ten opsigte van sodanige medisyne, komplementêre medisyne, veterinêre medisyne of toestel of enige klas of kategorie daarvan uitgereik word.

(9) Enige registrasie ingevolge hierdie artikel, insluitende 'n herregistrasie ingevolge subartikel (7), moet in openbare belang en ten einde die gehalte, veiligheid en doeltreffendheid van die medisyne, komplementêre medisyne, veterinêre medisyne of toestel te verseker en ten einde verslae oor verdagte ongewenste geneesmiddeleffekte te hersien, moet geldig wees vir sodanige tydperk as wat deur die Owerheid bepaal word en kan onderworpe wees aan sodanige voorwaardes as wat die Owerheid bepaal.

(10) Geen herregistrasie ingevolge subartikel (7) word gedoen nie, en geen voorwaarde in subartikel (6) beoog word bepaal nie, alvorens die houer van 'n registrasiesertifikaat genooi is om vertoë te rig oor waarom die herregistrasie in subartikel (7) beoog of die voorwaardes in subartikel (6) beoog nie deur die Owerheid bepaal of opgelê moet word nie, of nie in die formulering moet wees wat die Owerheid beoog nie, maar indien die houer van 'n registrasiesertifikaat nie sulke vertoë gerig het nie binne 'n tydperk van een maand na ontvangs daarvan deur hom of haar van die Owerheid se uitnodiging, of indien die Owerheid na oorweging van enige sodanige vertoë steeds van mening is dat die medisyne, komplementêre medisyne, veterinêre medisyne of toestel aan registrasie onttrek moet word of die voorwaarde wat hy beoog, bepaal en opgelê moet word, moet hy die medisyne, komplementêre medisyne, veterinêre medisyne of toestel aan registrasie onttrek en kan hy daarna, en behoudens subartikels (2) en (3), dit herregistreer behoudens enige voorwaarde wat hy beoog.

(11) Die Owerheid moet die houer van 'n registrasiesertifikaat skriftelik in kennis stel van sy besluit om 'n registrasie van die ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, veemiddel of toestel in te trek of om dit te herregistreer behoudens enige voorwaarde, en moet sodanige besluit by kennisgewing in die *Staatskoerant* bekend maak, maar geen sodanige kennisgewing mag gegee word nie indien die houer van 'n registrasiesertifikaat 'n appèl ingevolge artikel 26 teen sodanige

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. (1) 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 subsection (1), 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, at the expiration of that period; or

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

besluit van die Owerheid ingedien het, en verder indien 'n appèl wat aldus ingedien is verwerp word, moet die Owerheid voortgaan met die kennisgewing so gou moontlik nadat die besluit waarby die appèl verwerp is, geneem is.

(12) Die Owerheid kan, op aansoek van die houer van 'n registrasiesertifikaat, en as daar goeie rede is om dit te doen, en mits sodanige aansoek in die voorgeskrewe vorm is en vergesel gaan van die voorgeskrewe gelde, 'n inskrywing in die register wysig. Vir doeleindes van hierdie subartikel kan "goeie rede" insluit die behoefte om die registrasiesertifikaat aan 'n ander persoon oor te dra.

(13) Ondanks subartikel (6) kan die Owerheid na oorweging van die vertoë van 'n houer van 'n registrasiesertifikaat enige registrasie ingevolge hierdie Wet intrek indien hy van mening is dat—

(i) die houer van die registrasiesertifikaat of die agent van sodanige houer versuim het om te voldoen aan die voorwaarde waaraan die medisyne, komplementêre medisyne, veterinêre medisyne of toestel onderworpe is; of

(ii) 'n medisyne, komplementêre medisyne, veterinêre medisyne of toestel nie meer aan 'n voorgeskrewe vereiste voldoen nie; of

(iii) na 'n evaluasie van sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel, dit nie meer in openbare belang is om dit vir die publiek beskikbaar te hê nie.

(14) Die Owerheid moet die houer van 'n registrasiesertifikaat, die Raad vir Gesondheidsberoepe van Suid-Afrika, die Suid-Afrikaanse Veterinêre Raad, die Suid-Afrikaanse Aptekersraad, die Interim Koördinerende Komitee van Tradisionele Mediese Praktisyns van Suid-Afrika en die Suid-Afrikaanse Raad op Verpleging skriftelik in kennis stel en sy besluit om die registrasie in te trek en die redes ingevolge subartikel (12) vir sodanige intrekking, by kennisgewing in die *Staatskoerant* bekend maak.

(15) Die Owerheid se besluit om die registrasie in te trek, is onderworpe aan 'n appèl ingevolge artikel 26.

Verbod op die vervaardiging, verpakking, verspreiding, bemarking en verkoop van medisyne, komplementêre medisyne, veterinêre medisyne en toestelle wat onderworpe is aan registrasie en nie geregistreer is nie

25. (1) Behoudens die bepalings van hierdie artikel of artikels 30, 31 en 32 is dit 'n misdryf strafbaar met 'n boete of gevangenisstraf van hoogstens 10 jaar of met sowel sodanige boete as gevangenisstraf, om medisyne, komplementêre medisyne, veterinêre medisyne of toestelle wat aan registrasie onderworpe is en wat nie geregistreer is nie of wat nie aan die voorgeskrewe vereistes voldoen nie, te vervaardig, te verpak, te versprei, te bemark of te verkoop.

(2) Sonder om die wye omvang van subartikel (1) in te kort, kan die Owerheid van tyd tot tyd by resolusie wat deur die Minister goedgekeur is, bepaal dat 'n ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel of klas of kategorie ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel of deel van enige klas of kategorie ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel in die resolusie vermeld, onderworpe is aan registrasie ingevolge hierdie Wet.

(3) Enige sodanige resolusie kan ook betrekking hê net op medisyne, komplementêre medisyne, veterinêre medisyne of toestelle wat vir verkoop in die Republiek beskikbaar was onmiddellik voor die datum waarop dit in werking tree ingevolge subartikel (4) of net op ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of 'n toestel wat toe nie aldus beskikbaar was nie.

(4) Enige sodanige resolusie tree in werking wanneer dit in die *Staatskoerant* gepubliseer word.

(5) In die geval van 'n medisyne, komplementêre medisyne, veterinêre medisyne of toestel wat vir verkoop in die Republiek beskikbaar was onmiddellik voor die datum van publikasie in die *Staatskoerant* van die resolusie in gevolge waarvan dit aan registrasie ingevolge hierdie Wet onderworpe is, tree die bepalings van subartikel (1) in werking—

(a) indien daar nie binne die tydperk van ses maande onmiddellik na daardie datum om die registrasie van sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel aansoek gedoen word nie, by verstryking van daardie tydperk; of

(b) indien daar binne gemelde tydperk om die registrasie van sodanige ortodokse

medicine, veterinary medicine, or device is made within the said period, on the date one month after the date on which a 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 on 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), veterinarian 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.

medisyne, komplementêre medisyne, veterinêre medisyne of toestel aansoek gedoen word, op die datum een maand na die datum waarop 'n kennisgewing rakende die verwerping van die aansoek om registrasie van sodanige medisyne, komplementêre medisyne, veterinêre medisyne of toestel in die *Staatskoerant* gepubliseer word.

(6) Subartikel (1) is nie van toepassing nie ten opsigte van die verkoop van enige medisyne, komplementêre medisyne of veterinêre medisyne—

(a) toeberei in die loop van die verrigting van sy of haar professionele bedrywighede deur 'n apteker, apteker-intern of aptekersondersteuningspersoneel, ooreenkomstig die omvang van die praktyk van die personeel wat ingevolge die Wet op Aptekers, 1974 (Wet No. 53 van 1974), voorgeskryf word veearts of persoon wat die houer is van 'n lisensie beoog in artikel 33 vir 'n bepaalde pasiënt in 'n hoeveelheid nie groter nie as die hoeveelheid wat nodig is vir behandeling soos bepaal deur die mediese praktisyn, apteker, praktisyn of veearts; of

(b) toeberei deur 'n apteker in 'n hoeveelheid nie groter nie as wat voorgeskryf is vir verkoop in die kleinhandel, behoudens die voorwaardes insgelyks voorgeskryf of in 'n hoeveelheid vir 'n bepaalde persoon of dier soos voorgeskryf deur 'n mediese praktisyn of 'n tandarts of 'n veearts of 'n praktisyn of 'n verpleegkundige of ander persoon wat ingevolge die Wet op Gesondheidsberoepe, 1974 (Wet No. 65 van 1974), geregistreer is, en in artikel 31 bedoel, na gelang van die geval, indien sodanige medisyne geen bestanddeel bevat waarvan die verkoop deur hierdie Wet verbied word of enige bestanddeel bevat ten opsigte waarvan 'n aansoek om registrasie verwerp is en nie geadverteer is of word nie, maar die aktiewe bestanddele van sodanige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne voorkom in 'n ander ortodokse medisyne, komplementêre medisyne of veterinêre medisyne wat ingevolge hierdie Wet geregistreer is.

Appèl teen besluit van Owerheid

26. (1) Die Minister moet 'n Appèlraad aanstel wat onpartydig en onafhanklik van die Owerheid moet wees en wat moet bestaan uit 'n maksimum van vyf geskik gekwalifiseerde persone wat gepaste en geskikte persone is om aldus aangestel te word, maar die voorsitter daarvan moet 'n persoon wees wat op grond van daardie persoon se kennis van die reg aangestel is.

(2) Die lede van die Appèlraad wat nie in die voltydse diens van die Staat is nie, kan sodanige besoldiging en toelaes betaal word as wat die Minister met die instemming van die Minister van Finansies bepaal.

(3) Behoudens subartikel (4) moet die Appèlraad alle appèlle aanhoor en beslis van persone wat gegrief is deur enige besluit van die Owerheid, insluitende 'n besluit om 'n medisyne, komplementêre medisyne, veterinêre medisyne of 'n toestel nie te registreer nie of om enige sodanige registrasie in te trek.

(4) Die Minister moet by regulasie die reëls en prosedures wat deur die Appèlraad gevolg moet word by die aanhoor van appèlle, insluitende die bevoegdheid om te weier om 'n appèl aan te hoor indien hy van mening is dat die appellant kwelsugtig is of dat daar geen werklike gronde vir appèl is nie, en die getal lede van die Appèlraad wat 'n appèl kan aanhoor, bepaal.

Verstrekking van inligting rakende ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of toestelle aan die Owerheid

27. Die Owerheid kan by skriftelike kennisgewing van enige persoon wat enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of toestel vervaardig of verkoop of toedien, voorskryf of resepteer, of op wie se instruksie enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of toestel vervaardig of verkoop of toegedien of voorgeskryf word, vereis om binne 'n tydperk wat in sodanige kennisgewing vermeld word, enige inligting wat sodanige persoon in sy of haar besit het of wat sodanige persoon in 'n posisie is om te verkry betreffende sodanige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of toestel, aan hom te verstrek, maar die Owerheid, indien aldus versoek deur enige persoon aan wie sodanige kennisgewing gerig is, kan die tydperk wat in sodanige kennisgewing vermeld is, verleng.

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. (1) No person may sell any orthodox medicine, 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. (1) 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 the 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 (1)*(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. (1) 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.

HOOFSTUK V

MAATREËLS OM ETIKETTE EN ADVERTERING, DIE VERKOOP VAN ONGEREGISTREERDE MEDISYNE, KOMPLEMENTERE MEDISYNE, VETERINERE MEDISYNE EN TOESTELLE TE BEHEER EN BEHEER OOR MEDISYNE, KOMPLEMENTERE MEDISYNE, VETERINERE MEDISYNE EN TOESTELLE

Etikette en advertensies

28. (1) Niemand mag enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne, mediese toestel, of gelyste stof verkoop nie tensy die onmiddellike houer van die verpakking waarin daardie ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, toestel of gelyste stof verkoop word, 'n etiket op het waarin die voorgeskrewe besonderhede vermeld word.

(2) Niemand mag enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, toestel of gelyste stof vir verkoop adverteer nie tensy sodanige advertensie aan die voorgeskrewe vereistes voldoen.

(3) Die Owerheid moet die etiket in subartikel (1) beoog, goedkeur.

(4) Die Owerheid kan 'n afwyking van die voorgeskrewe formaat en inhoud van enige etiket magtig.

(5) Die Minister kan, in oorleg met die Owerheid, bykomende vereistes vir die etikettering van medisyne voorskryf.

Publikasie of verspreiding van vals advertensie rakende ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestelle

29. (1) Niemand mag—

(a) enige vals of misleidende advertensie rakende enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel, hetsy geregistreer al dan nie, publiseer of versprei of op enige ander wyse hoegenaamd onder die aandag van die publiek bring of veroorsaak of toelaat dat dit gepubliseer of versprei of aldus onder die aandag van die publiek gebring word nie; of

(b) in enige advertensie enige aanspraak maak ten effekte dat die terapeutiese doeltreffendheid en gevolg van enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel anders is as soos verklaar deur die Owerheid ingevolge artikel 24(6)*(b)*, of verklaar of te kenne gee dat enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel gebruik moet word vir 'n doel of onder omstandighede of op 'n wyse anders as soos verklaar deur die Owerheid ingevolge artikel 24(6)*(c)*.

(2) Dit is 'n voldoende verweer in enige vervolging vir 'n misdryf ingevolge subartikel (1)*(a)* as daar tot tevredenheid van die hof bewys word dat die beskuldigde, wat nie 'n verkoper is nie van die ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel waarop die vals of misleidende advertensie wat die onderwerp van die vervolging is, betrekking het, nie geweet het nie en daar nie redelikerwys van hom of haar verwag kon word om te weet nie dat die advertensie in enige opsig vals of misleidend is, tensy daar bewys word dat die beskuldigde versuim het om op versoek van die Owerheid of 'n inspekteur of 'n lid van die Suid-Afrikaanse Polisiediens die naam en adres te verstrek van die persoon op wie se aandrang die advertensie gepubliseer, versprei of aldus onder die aandag van die publiek gebring is.

Magtiging deur die Owerheid van die verkoop van ongeregistreerde ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel vir sekere doeleindes

30. (1) Die Owerheid kan enige persoon skriftelik magtig om gedurende 'n bepaalde tydperk 'n bepaalde hoeveelheid van enige bepaalde ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel wat nie geregistreer is nie, aan enige bepaalde persoon of instelling te verkoop.

(2) Enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel wat verkoop is kragtens enige magtiging ingevolge subartikel (1), kan net gebruik word vir sodanige doeleindes en op sodanige wyse en gedurende sodanige tydperk as wat die Owerheid skriftelik bepaal.

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

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

31. (1) Subject to this section, no person may sell, 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 referred to in this section; and

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

(3) Any Schedule 0 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 dealer 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 contemplated in section 33;

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

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

(aa) prescribe only the Scheduled substances 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 14 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;

(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 such 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 such 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;

(3) Die Owerheid kan te eniger tyd by skriftelike kennisgewing enige magtiging wat kragtens subartikel (1) verleen is, intrek indien daar nie uitvoering gegee word nie aan enige bepaling ingevolge subartikel (2).

Beheer oor ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, toestelle en gelyste stowwe

31. (1) Behoudens hierdie artikel mag niemand enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, toestelle of gelyste stof verkoop, in sy of haar besit hê of vervaardig nie, uitgesonderd in ooreenstemming met die voorgeskrewe voorwaardes.

(2) Die Minister kan, op aanbeveling van die Owerheid—

(a) die Gelyste stowwe in hierdie artikel bedoel voorskryf; en

(b) sodanige Bylaes wat die Minister ooreenkomstig hierdie artikel nodig ag, voorskryf.

(3) Enige Bylae 0-stof mag in 'n oop winkel verkoop word.

(4) Enige Bylae 1-stof mag nie verkoop word nie—

(a) deur 'n ander persoon as—

(i) 'n apteker, apteker-intern of aptekersondersteuningpersoneel, ooreenkomstig die omvang van die praktyk van die personeel wat ingevolge die Wet op Aptekers, 1974 (Wet No. 53 van 1974), voorgeskryf word;

(ii) 'n vervaardiger van of 'n groothandelaar in farmaseutiese produkte vir verkoop aan enige persoon wat sodanige stof wettig mag besit;

(iii) 'n mediese praktisyn of tandarts, wat—

(aa) sodanige stof mag voorskryf; en

(bb) sodanige stof kan toeberei en resepteer slegs indien daardie persoon die houer is van 'n lisensie soos beoog in artikel 33;

(iv) 'n veearts wat sodanige stof kan voorskryf, toeberei of resepteer;

(v) 'n praktisyn, verpleegkundige of 'n persoon wat ingevolge die Wet op Gesondheidsberoepe, 1974, geregistreer is, uitgesonderd 'n mediese praktisyn of tandarts, wat—

(aa) slegs die gelyste stowwe kan voorskryf wat vir daardie doel in die Bylae geïdentifiseer is; en

(bb) die gelyste stowwe in item *(aa)* bedoel kan toeberei en resepteer slegs indien hy of sy die houer is van 'n lisensie in artikel 33 beoog;

(b) aan enige persoon oënskynlik onder die ouderdom van 14 jaar, uitgesonderd op 'n voorskrif uitgereik deur 'n gemagtigde voorskrywer en geresepteer deur 'n apteker, apteker-intern of aptekersondersteuningspersoneel, ooreenkomstig die omvang van die praktyk van sodanige personeel soos ingevolge die Wet op Aptekers, 1974, voorgeskryf of deur 'n veearts of 'n persoon wat die houer is van 'n lisensie in artikel 33 beoog, of op 'n skriftelike bestelling wat die doel toon waarvoor sodanige stof gebruik staan te word en 'n handtekening bevat wat aan die verkoper bekend is as die handtekening van 'n persoon wat aan sodanige verkoper bekend is en wat oënskynlik bo die ouderdom van 14 jaar is;

(c) tensy die verkoper, uitgesonderd 'n vervaardiger van of groothandelaar in farmaseutiese produkte, in 'n voorskrifboek wat op 'n voorgeskrewe wyse gehou moet word, die voorgeskrewe besonderhede van sodanige verkoping aanteken.

(5) Enige Bylae 2-, Bylae 3-, Bylae 4-, Bylae 5- of Bylae 6-stof mag deur niemand anders verkoop word nie as—

(a) 'n apteker, apteker-intern of aptekersondersteuningpersoneel, ooreenkomstig die omvang van die praktyk van sodanige personeel wat ingevolge die Wet op Aptekers, 1974, voorgeskryf word, en wat net Bylae 2-stowwe sonder 'n voorskrif kan verkoop;

(b) 'n apteker, 'n apteker-intern of aptekersondersteuningpersoneel ooreenkomstig die omvang van die praktyk van die personeel wat ingevolge die Wet op Aptekers, 1974, word, wat net Bylae 2-stowwe sonder 'n voorskrif kan verkoop, op 'n skriftelike voorskrif uitgereik deur 'n gemagtigde voorskrywer of op die mondelinge instruksies van 'n gemagtigde voorskrywer wat aan sodanige apteker bekend is;

(c) 'n vervaardiger van of 'n groothandelaar in farmaseutiese produkte vir verkoop aan enige persoon wat sodanige stof wettig mag besit;

(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 of 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 must 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 days 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 be dispensed;

(e) in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of 14 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 psychiatrist, 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;

(d) 'n mediese praktisyn of tandarts, wat—

(i) sodanige stof mag voorskryf;

(ii) sodanige stof mag toeberei of resepteer slegs indien hy of sy die houer is van 'n lisensie in artikel 33 beoog;

(e) 'n veearts wat sodanige stof mag voorskryf, toeberei of resepteer;

(f) 'n praktisyn, 'n verpleegkundige of 'n persoon wat ingevolge die Wet op Gesondheidsberoepe, 1974, geregistreer is, uitgesonderd 'n mediese praktisyn of tandarts, wat—

(i) sodanige stof mag voorskryf; en

(ii) sodanige stof mag toeberei of resepteer slegs indien hy of sy die houer is van 'n lisensie in artikel 33 beoog.

(6) Enige verkoping ingevolge subartikel (5) mag plaasvind slegs op voorwaarde dat—

(a) al die voorgeskrewe besonderhede van elke verkoping op die voorgeskrewe wyse aangeteken word in 'n voorskrifboek of ander permanente rekord wat op die voorgeskrewe wyse gehou moet word;

(b) die gemagtigde voorskrywer wat mondelinge instruksies aan 'n apteker gegee het om 'n voorskrif te resepteer, binne sewe dae nadat sodanige instruksies gegee is, sodanige apteker moet voorsien van 'n voorskrif wat sodanige instruksies bevestig;

(c) in die geval van mondelinge instruksies, die behandelingstydperk nie meer as sewe dae mag wees nie;

(d) indien 'n voorskrif nie binne 30 dae na uitreiking aangebied word vir reseptering nie, dit nie geresepteer mag word nie;

(e) in die geval van 'n Bylae 2-stof, sodanige stof nie aan 'n persoon oënskynlik onder die ouderdom van 14 jaar verskaf mag word nie, uitgesonderd op 'n voorskrif uitgereik deur 'n gemagtigde voorskrywer en gerespteer deur 'n apteker, apteker-intern of aptekersondersteuningspersoneel, ooreenkomstig die omvang van die praktyk van sodanige personeel soos ingevolge die Wet op Aptekers, 1974, voorgeskryf, of deur 'n veearts of 'n persoon wat die houer is van 'n lisensie in artikel 33 beoog, of op 'n skriftelike bestelling wat die doel toon waarvoor sodanige stof gebruik staan te word en 'n handtekening bevat wat aan die verkoper bekend is as die handtekening van 'n persoon wat aan sodanige verkoper bekend is en wat oënskynlik bo die ouderdom van 14 jaar is;

(f) in die geval van 'n Bylae 2-, Bylae 3- of Bylae 4-stof, sodanige verkoping herhaal kan word as die persoon wat die voorskrif uitgereik het, die getal kere dat dit geresepteer kan word, daarop aangedui het, maar nie vir langer as ses maande nie;

(g) in die geval van 'n Bylae 5-stof, sodanige verkoping nie vir langer as ses maande herhaal mag word nie, en dan slegs as die gemagtigde voorskrywer die getal kere en die tussenpose waarteen dit verskaf kan word, aangedui het;

(h) waar 'n Bylae 5-stof gebruik word vir—

(i) sy angsverligtende, antidepressante of sussende eienskappe, dit nie vir langer as ses maande voorgeskryf mag word nie tensy die gemagtigde voorskrywer 'n geregistreerde psigiater of, in die geval van 'n psigiater, 'n ander psigiater geraadpleeg het alvorens 'n nuwe voorskrif uitgereik word;

(ii) sy analgetiese eienskappe, dit nie vir langer as ses maande voorgeskryf mag word nie tensy die gemagtigde voorskrywer 'n ander mediese praktisyn geraadpleeg het alvorens 'n nuwe voorskrif uitgereik word;

(i) in die geval van 'n Bylae 6-stof, dit nie herhaal mag word nie sonder dat 'n nuwe voorskrif uitgereik word;

(j) in 'n noodgeval waar die gesondheid of lewe van 'n pasiënt op die spel is, 'n apteker in die groothandelpraktyk, by ontvangs van 'n telefoniese of telefaks- of ander elektroniese versoek, 'n Bylae 6-stof aan 'n apteker, mediese praktisyn, tandarts, veearts, praktisyn, verpleegkundige of ander persone wat ingevolge die Wet op Gesondheidsberoepe, 1974, geregistreer is, sonder 'n skriftelike bestelling kan verskaf, maar—

(i) dit is die verantwoordelikheid van sodanige apteker, mediese praktisyn, tandarts, veearts, praktisyn, verpleegkundige of ander persoon om te verseker dat sodanige apteker binne sewe dae 'n skriftelike bestelling ontvang;

(ii) the Schedule 6 substance must be supplied 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 sell any Schedule 5 or Schedule 6 substance in any quantity not greater than that 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 the 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 therapy be continued, and that the particulars of such sale are recorded in a prescription book or other prescribed permanent record;

(m) 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 pack 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;

(n) 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 if 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

(r) any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance for the treatment of any animal may be supplied by any person practising 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

(ii) die Bylae 6-stof in die kleinste beskikbare eenheidverkoopspak verskaf word;

(iii) 'n permanente rekord van sodanige verskaffing gemaak en gehou word;

(k) in 'n noodgeval 'n apteker enige Bylae 5- of Bylae 6-stof kan verkoop in enige hoeveelheid nie groter nie as wat nodig is vir aaneenlopende gebruik vir 'n tydperk van 48 uur, op die mondelinge instruksies van 'n mediese praktisyn, tandarts, veearts, praktisyn, verpleegkundige of ander persone wat ingevolge die Wet op Gesondheidsberoepe, 1974, geregistreer is, wat aan sodanige apteker bekend is, maar die voorskrywer wat sodanige mondelinge instruksies gegee het, moet 'n skriftelike voorskrif wat die instruksies bevestig aan sodanige apteker verskaf binne 72 uur nadat sodanige instruksies gegee is;

(l) in 'n noodgeval 'n apteker 'n Bylae 2-, Bylae 3- of Bylae 4-stof op 'n nie-herhalende grondslag kan verkoop vir 'n tydperk van hoogstens 30 dae in ooreenstemming met die oorspronklike voorskrif ten einde te verseker dat die terapie nie ontwrig word nie as hy of sy seker is dat 'n gemagtigde voorskrywer die terapie begin het, met die bedoeling dat die terapie voortgesit word, en die besonderhede van sodanige verkoping moet in 'n voorskrifboek of ander permanente rekord aangeteken word;

(m) 'n apteker 'n groter of kleiner hoeveelheid van 'n Bylae 1-, Bylae 2-, Bylae 3- of Bylae 4-stof kan verkoop as die hoeveelheid wat voorgeskryf of bestel is, volgens die terapeutiese pak in die oorspronklike houer van sodanige stof soos aan die apteker verskaf, maar die hoeveelhede aldus verkoop mag nie 25 persent van die hoeveelheid wat in die onderhawige voorskrif of bestelling vermeld is nie;

(n) enige verkoper in hierdie subartikel bedoel die onderhawige voorskrif of bestelling moet behou vir 'n tydperk van ten minste vyf jaar na die datum van sodanige verkoping;

(o) 'n Bylae 6-stof verkoop mag word slegs indien die behandeling nie meer as 30 opeenvolgende dae is nie;

(p) die verkoop van 'n Bylae 5- of Bylae 6-stof deur 'n vervaardiger van of 'n groothandelaar in farmaseutiese produkte aangeteken moet word in 'n register wat op die voorgeskrewe wyse gehou moet word, en gebalanseer moet word om die hoeveelheid van elke Bylae 5- of Bylae 6-stof wat in voorraad oorbly soos op die laaste dag van Maart, Junie, September en Desember van elke jaar duidelik te toon, en sodanige balansering binne 14 dae na elk van die gemelde datums afgehandel moet word;

(q) 'n apteker die datum van verkoping en die hoeveelheid van die stof wat verkoop is op die voorskrif moet aanteken, en wanneer dit herhaal word, die datum van verkoop en die hoeveelheid van die gemelde stof wat verkoop is, en dat die laaste verkoper die voorskrif moet hou vir 'n tydperk van ten minste vyf jaar na die datum van laaste verkoop;

(r) enige Bylae 1-, Bylae 2-, Bylae 3- of Bylae 4-stof vir die behandeling van enige dier verskaf kan word deur enige persoon wat 'n para-veterinêre professie beoefen binne die betekenis van die Wet op Veterinêre en Para-veterinêre Beroepe, 1982 (Wet No. 19 van 1982), op 'n skriftelike voorskrif uitgereik deur 'n veearts of op die mondelinge instruksies van 'n veearts.

(7) *(a)* Niemand, uitgesonderd 'n apteker, of 'n apteker-intern of aptekersondersteuningspersoneel, ooreenkomstig die omvang van die praktyk van sodanige personeel soos ingevolge die Wet op Aptekers, 1974, voorgeskryf, mag 'n Bylae 1-, Bylae 2-, Bylae 3-, Bylae 4-, Bylae 5- of Bylae 6-stof vir ontledingsdoeleindes, die vervaardiging van voedsel, kosmetiekware, opvoedkundige of wetenskaplike doeleindes verkoop of uitvoer nie tensy 'n permit, uitgereik in ooreenstemming met die voorgeskrewe voorwaardes, behoudens paragraaf *(b)* vir sodanige doeleindes van die Owerheid verkry is.

(b) Die Owerheid kan enige permit in paragraaf *(a)* bedoel intrek indien die voorwaardes waarop sodanige permit uitgereik is, nie nagekom word nie of indien dit nie in openbare belang is dat die bepaalde handeling voortduur nie.

(8) Behoudens subartikel (9) mag 'n Bylae 7-stof nie deur enige ander persoon as die Direkteur-generaal verkry word nie met die doel om dit aan 'n mediese praktisyn of veearts te verskaf, op die voorgeskrewe voorwaardes, vir die behandeling van 'n

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)*.

bepaalde pasiënt van daardie mediese praktisyn of veearts op sodanige voorwaardes as wat die Direkteur-generaal, op aanbeveling van die Owerheid, bepaal.

(9) *(a)* Niemand mag—

(i) enige Bylae 7-stof verkry, gebruik, besit, ontwikkel, vervaardig of verskaf, of enige Bylae 6-stof vervaardig nie tensy 'n permit vir sodanige verkryging, gebruik, besit, vervaardiging of verskaffing deur die Owerheid aan daardie persoon uitgereik is, maar die Owerheid kan, behoudens sodanige voorwaardes as wat hy bepaal, die gebruik van enige Bylae 7-stof verkry of magtig ten einde dit op die voorgeskrewe voorwaardes aan 'n mediese praktisyn, ontleder, navorser of veearts te verskaf vir die behandeling of voorkoming van 'n mediese toestand in 'n bepaalde pasiënt, of vir doeleindes van opvoeding, ontleding of navorsing;

(ii) enige Bylae 5- of Bylae 6-stof vir ander doeleindes as medisinale doeleindes vervaardig, gebruik of verskaf nie tensy 'n permit vir sodanige vervaardiging, gebruik of verskaffing op die voorgeskrewe voorwaardes deur die Owerheid aan hom of haar uitgereik is.

(b) Ondanks paragraaf *(a)* kan die Owerheid enige permit wat ingevolge daardie paragraaf uitgereik is, te eniger tyd intrek indien enige voorwaarde waarop die permit uitgereik is, nie nagekom is nie.

(c) 'n Permit uitgereik ingevolge hierdie subartikel is geldig vir 'n tydperk van 12 kalendermaande na die datum van uitreiking daarvan.

(10) Ondanks andersluidende bepalings vervat in hierdie artikel mag niemand enige gelyste stof of ortodokse medisyne, komplementêre medisyne of veterinêre medisyne vir ander doeleindes as medisinale doeleindes verkoop of toedien nie, maar die Minister kan, behoudens die voorwaardes of vereistes vermeld in sodanige magtiging, die toediening buite enige hospitaal magtig van enige gelyste stof of medisyne vir die bevrediging of verligting van 'n gewoonte of drang aan die persoon in sodanige magtiging bedoel.

(11) *(a)* Niemand mag enige Bylae 6- of Bylae 7-stof of ander stof of medisyne wat vir daardie doel voorgeskryf is, invoer of uitvoer nie tensy 'n permit op die voorgeskrewe wyse en behoudens die voorgeskrewe voorwaardes deur die Owerheid aan daardie persoon uitgereik is.

(b) 'n Permit in paragraaf *(a)* bedoel, kan uitgereik word vir enige ander doel as vir die bevrediging of verligting van 'n gewoonte of drang ten opsigte van sodanige stof of ortodokse medisyne.

(c) Die uitreiking van 'n permit in paragraaf *(a)* bedoel, kan geweier word indien—

(i) die Owerheid nie oortuig is nie dat die aansoeker in staat is om die stof of medisyne op 'n bevredigende wyse te hou of te berg nie ten einde die verlies daarvan te voorkom;

(ii) die gebruik van sodanige stof of ortodokse medisyne of veterinêre medisyne nie ingevolge hierdie Wet gemagtig is nie;

(iii) die Owerheid van mening is dat die jaarlikse invoerkwota vir sodanige stof oorskry is of oorskry sal word;

(iv) die Owerheid van mening is dat sodanige stof of ortodokse medisyne of veterinêre medisyne van 'n aanvaarbare gehalte reeds in die Republiek beskikbaar is; of

(v) die aansoeker nie voldoen het nie aan die voorwaardes waarop 'n vorige permit aan daardie aansoeker uitgereik is.

(d) Indien 'n aansoek geweier word, moet die redes vir sodanige weiering aan die aansoeker verstrek word.

(e) 'n Permit uitgereik ingevolge hierdie subartikel is geldig vir 'n tydperk van ses maande na die datum van uitreiking daarvan.

(12) *(a)* Die beheer oor die invoer van gelyste stowwe het betrekking op—

(i) enige Bylae 6- of Bylae 7-stof;

(ii) sodanige stowwe ongeag die skeduleringstatus daaraan toegeken, as wat die Minister voorskryf;

(iii) enige ander stof wat aan internasionale beheer onderworpe raak ingevolge die Enkel Konvensie oor Narkotiese Dwelms van 1961 of die Konvensie oor Psigotropiese Stowwe van 1971 wat deur die Republiek onderteken is.

(b) Die verkryging van invoerpermitte soos vereis ingevolge subartikel (11) is nie van toepassing nie op enige preparaat wat 'n stof bevat soos voorgeskryf wat uitdruklik vrygestel is van alle beheermaatreëls vir die verkryging van sodanige invoerpermit deur die Enkel Konvensie oor Narkotiese Dwelms van 1961 in paragraaf *(a)* bedoel.

(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, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, 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 0, 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.

(c) Ondanks paragraaf *(b)* mag geen sodanige invoer plaasvind nie tensy dit deur die Owerheid gemagtig is.

(13) Enige permit uitgereik ingevolge subartikel (11) is onderworpe—

(a) daaraan dat die aansoeker die Owerheid jaarliks van die voorgeskrewe inligting voorsien;

(b) aan die vereiste dat daar geen afwyking van die besonderhede wat op die permit verskyn, mag wees nie, maar indien die hoeveelheid van sodanige ortodokse medisyne of veterinêre medisyne wat ingevoer moet word minder is as waarvoor die permit voorsiening maak, moet die Owerheid skriftelik daarvan in kennis gestel word binne 10 dae na die invoer van sodanige stof of ortodokse medisyne, komplementêre medisyne of veterinêre medisyne; en

(c) aan die nakoming van die voorwaardes, soos in die permit uiteengesit, en die sertifisering van die triplikaatafskrif van die permit deur 'n doeanebeampte of 'n werknemer van die SA Poskantoor Beperk.

(14) Ondanks enige andersluidende bepaling in hierdie artikel—

(a) mag 'n aptekersassistent geen Bylae 6-stof hanteer nie behalwe soos beoog in subartikel (5)*(a)* en *(b)*; en

(b) mag geen verpleegkundige of 'n persoon wat kragtens die Wet op Gesondheidsberoepe, 1974, geregistreer is, uitgesonderd 'n mediese praktisyn of tandarts, 'n ortodokse medisyne of gelyste stof voorskryf nie tensy daardie verpleegkundige of persoon deur sy of haar betrokke beroepsraad gemagtig is om dit te doen.

(15) Ondanks enige andersluidende bepalings in hierdie artikel kan die Owerheid, na oorleg met die Interim Aptekersraad van Suid-Afrika soos bedoel in artikel 2 van die Wet op Aptekers, 1974 (Wet No. 53 van 1974), 'n permit uitreik aan enige persoon of organisasie wat 'n gesondheidsdiens verrig, waardeur sodanige persoon of organisasie gemagtig word om enige bepaalde Bylae 1-, Bylae 2-, Bylae 3-, Bylae 4- of Bylae 5-stof te verkry, te besit, te gebruik of te verskaf, en sodanige permit is onderworpe aan sodanige voorwaardes as wat die Owerheid bepaal.

(16) Ondanks enige andersluidende bepalings in hierdie artikel—

(a) kan enige persoon 'n Bylae 0-, Bylae 1- of Bylae 2-stof vir medisinale doeleindes besit;

(b) kan enige persoon 'n Bylae 3-, Bylae 4-, Bylae 5-, Bylae 6- of Bylae 7-stof besit indien hy of sy 'n voorskrif verkry het wat deur 'n gemagtigde voorskrywer uitgereik is;

(c) kan enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stof besit word deur 'n mediese praktisyn, tandarts, veearts, praktisyn, verpleegkundige of ander persoon geregistreer kragtens die Wet op Gesondheidsberoepe, 1974, of kragtens die Wet op Veterinêre en Para-veterinêre Beroepe, 1982, met die doel om dit toe te dien in ooreenstemming met sy of haar praktykbestek;

(d) kan enige medisyne of gelyste stof besit word vir verkoop deur 'n apteker, 'n persoon gelisensieer om 'n apteek te besit ingevolge die Wet op Aptekers, 1974, of 'n persoon wat die houer is van 'n lisensie soos in artikel 33 beoog.

(17) Vir doeleindes van hierdie artikel beteken—

(a) "gemagtigde voorskrywer" 'n mediese praktisyn, tandarts, veearts, praktisyn, verpleegkundige of ander persoon geregistreer kragtens die Wet op Gesondheidsberoepe, 1974; en

(b) "medisinale doel" vir die doel van die behandeling of voorkoming van 'n siekte of die een of ander definitiewe genesende of terapeutiese doel, maar sluit dit nie die bevrediging of verligting van 'n gewoonte of drang na die betrokke stof of na enige ander stof in nie, behalwe waar die stof toegedien of gebruik word in 'n hospitaal of soortgelyke inrigting wat in geheel of gedeeltelik deur die Staat of 'n provinsiale regering onderhou word of wat vir sodanige doel deur die Minister goedgekeur is.

(18) *(a)* Die Minister kan, op die aanbeveling van die Owerheid, voorwaardes vir die vervaardiging, verkoop en besit van mediese toestelle voorskryf; en

(b) Niemand mag 'n mediese toestel beoog in paragraaf *(a)* vervaardig, verkoop of in sy of haar besit hê nie behalwe in ooreenstemming met die voorgeskrewe voorwaardes.

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 said subsection.

(7) Subsections (5) and (6) come into operation six months after the 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;

Uitsluiting van enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of mediese toestel van die werking van hierdie Wet

32. Die Minister kan, op die eenparige aanbeveling van die lede teenwoordig op enige vergadering van die Raad, by kennisgewing in die *Staatskoerant*, behoudens sodanige voorwaardes as wat die Minister bepaal, enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of mediese toestel vrystel van die werking van enige van of al die bepalings van hierdie Wet, en kan op dieselfde wyse enige sodanige kennisgewing wysig of intrek.

Lisensiëring

33. (1) Behoudens die bepalings van hierdie artikel kan die Owerheid—

(a) op aansoek op die voorgeskrewe wyse en by betaling van die voorgeskrewe geld, aan 'n mediese praktisyn, tandarts, praktisyn, verpleegkundige of ander persoon geregistreer kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), 'n lisensie uitreik om medisyne te resepteer, op die voorgeskrewe voorwaardes;

(b) op aansoek op die voorgeskrewe wyse en by betaling van die voorgeskrewe geld, aan 'n vervaardiger van, groothandelaar in of verspreider van ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of mediese toestelle 'n lisensie uitreik om sodanige medisyne of mediese toestelle te vervaardig, as groothandelaar daarin op te tree of te versprei, na gelang van die geval, op sodanige voorwaardes rakende die toepassing van sodanige beginsels vir die versekering van aanvaarbare gehalte en goeie praktyke vir vervaardiging en verspreiding as wat die Owerheid bepaal.

(2) 'n Lisensie in subartikel (1)*(a)* bedoel, word nie uitgereik nie tensy die aansoeker 'n aanvullende kursus voorgeskryf ingevolge die Wet op Aptekers, 1974, deur die Suid-Afrikaanse Aptekersraad, suksesvol voltooi het.

(3) Die Owerheid kan van 'n aansoeker in subartikel (1) bedoel vereis om sodanige inligting, benewens enige inligting wat ingevolge dieselfde subartikel deur die aansoeker verstrek is, te verstrek as wat die Owerheid nodig ag.

(4) Wanneer die Owerheid 'n aansoek om 'n lisensie toestaan of weier—

(a) moet die aansoeker skriftelik daarvan in kennis gestel word; en

(b) in die geval van die weiering van 'n aansoek, moet die redes vir sodanige weiering aan die aansoeker verstrek word.

(5) Niemand mag 'n ortodokse medisyne, komplementêre medisyne of veterinêre medisyne toeberei of resepteer nie tensy daardie persoon daartoe gemagtig is ingevolge die Wet op Aptekers, 1974, of die houer is van 'n lisensie soos in subartikel (1)*(a)* beoog.

(6) Geen vervaardiger, groothandelaar of verspreider in subartikel (1)*(b)* bedoel, mag enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of mediese toestel vervaardig, as groothandelaar daarin optree of versprei nie, na gelang van die geval, tensy daardie persoon die houer is van 'n lisensie in dieselfde subartikel beoog.

(7) Subartikels (5) en (6) tree in werking ses maande na die inwerkingtreding van hierdie Wet.

Tydperk van geldigheid en hernuwing van lisensie

34. 'n Lisensie wat kragtens artikel 33 uitgereik is, is geldig vir die voorgeskrewe tydperk maar kan hernu word op aansoek op die voorgeskrewe wyse en voor die voorgeskrewe tyd of sodanige later tyd as wat die Owerheid toelaat en by betaling van die voorgeskrewe geld.

Opskorting en intrekking van lisensie

35. (1) Indien die houer van 'n lisensie ingevolge artikel 33—

(a) in verband met 'n aansoek om 'n lisensie of hernuwing van 'n lisensie die Owerheid voorsien het van inligting wat na die wete van sodanige houer in enige wesenlike opsig onwaar of misleidend is;

(b) 'n voorwaarde waarop die lisensie uitgereik is, oortree het of versuim het om daaraan te voldoen;

(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 the 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 if 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. (1) 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 (1) 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 conferred 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.

(c) 'n bepaling van hierdie Wet oortree het of versuim het om daaraan te voldoen;

(d) in die geval van 'n lisensie uitgereik kragtens artikel 34(1), te eniger tyd skuldig bevind is aan 'n misdryf wat van so 'n aard is dat dit hom of haar na die mening van die Owerheid ongeskik maak om medisyne te toe te berei of te resepteer;

kan die Owerheid, by wyse van 'n skriftelike kennisgewing, daardie persoon aansê om binne die tydperk in die kennisgewing vermeld, welke tydperk ten minste 20 dae na die datum van die kennisgewing moet wees, gronde aan te voer waarom die onderhawige lisensie nie opgeskort of ingetrek moet word nie.

(2) Die Owerheid kan na oorweging van die redes verstrek ingevolge subartikel (1)—

(a) die onderhawige lisensie opskort vir sodanige tydperk as wat die Owerheid bepaal; of

(b) die onderhawige lisensie intrek.

(3) Niemand is op die terugbetaling van enige voorgeskrewe geld ten opsigte van enige aansoek om die verlening of hernuwing van 'n lisensie geregtig nie indien sodanige aansoek geweier is of die lisensie opgeskort of ingetrek is.

Beskikking oor ongewenste ortodokse medisyne, komplementêre medisyne, veterinêre medisyne en mediese toestelle

36. (1) Indien die Owerheid van mening is dat dit nie in openbare belang is dat enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel aan die publiek beskikbaar gestel word nie, kan hy—

(a) by skriftelike kennisgewing wat per geregistreerde pos aan enige persoon gestuur word, daardie persoon gelas; of

(b) by kennisgewing in die Staatskoerant, enige persoon gelas,

om enige hoeveelheid van sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel wat daardie persoon in sy of haar besit het, terug te besorg aan die vervaardiger daarvan, of (in die geval van enige ingevoerde medisyne, komplementêre medisyne, veterinêre medisyne of toestel) aan die betrokke invoerder om dit aan enige ander persoon wat deur die Owerheid aangewys word, te lewer of te stuur.

(2) Die Owerheid kan by skriftelike kennisgewing enige vervaardiger of invoerder van enige sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestelle wat enige hoeveelheid daarvan in sy of haar besit het (insluitende enige hoeveelheid wat aan daardie persoon terugbesorg, gelewer of gestuur is ingevolge 'n opdrag kragtens subartikel (1)), of enige ander persoon aan wie enige hoeveelheid van sodanige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestelle aldus terugbesorg, gelewer of gestuur is, gelas om met daardie hoeveelheid te handel of daaroor te beskik op sodanige wyse as wat die Owerheid bepaal.

(3) Niemand mag enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestelle wat die onderwerp van 'n kennisgewing ingevolge subartikel (1) is wat nie op appèl ter syde gestel is nie, verkoop nie.

Ontleders, farmakoloë en patoloë

37. Die Owerheid kan sodanige gesag verleen aan sodanige ontleders, farmakoloë en patoloë as wat hy nodig ag vir die behoorlike toepassing van hierdie Wet.

Delegasie van bevoegdhede

38. Die Raad kan die Hoof- Uitvoerende Beampte of enige beampte van die Owerheid skriftelik magtig om enige van die bevoegdhede aan die Raad verleen by hierdie Wet, uitgesonder die bevoegdhede in artikels 6(2), 12, 16, 19, 21, 22, 28(4) en 30 bedoel, uit te oefen ten einde enige van die pligte of funksies wat ingevolge hierdie Wet aan die Raad opgelê is, uit te voer of te verrig.

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 for 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 act or 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 all reasonable steps to prevent the act or omission.

(2) Whenever any manager, agent or employee of any such employer does or omits to do an act which 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 enforcement 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—

Handeling of versuim deur bestuurder, agent of werknemer

39. (1) Telkens wanneer 'n bestuurder, agent of werknemer of enige persoon enige handeling verrig of versuim om dit te verrig wat 'n misdryf ingevolge hierdie Wet sou wees vir die werkgewer om te doen of te versuim om te doen, dan, tensy daar bewys word dat—

(a) deur daardie handeling te verrig of te versuim om dit te verrig, die bestuurder, agent of werknemer sonder die instemming of toestemming van die werkgewer opgetree het; en

(b) alle redelike stappe deur die werkgewer gedoen is om enige handeling of versuim van die onderhawige tipe te voorkom; en

(c) dit onder geen toestande of onder enige omstandighede binne die bestek van die gesag of in die loop van die diens van die bestuurder, agent of werknemer was om handelinge, hetsy wettig of onwettig, te verrig of te versuim om dit te verrig, van die aard van die onderhawige handeling of versuim,

word vermoed dat die werkgewer self daardie handeling verrig het of versuim het om dit te verrig, en kan hy of sy skuldig bevind en gevonnis word ten opsigte daarvan, en die feit dat die werkgewer opdrag gegee het om enige handeling of versuim van die onderhawige tipe te verbied, is nie op sigself aanvaarbaar as afdoende bewys dat die werkgewer alle redelike stappe gedoen het om die handeling of versuim te voorkom nie.

(2) Telkens wanneer enige bestuurder, agent of werknemer van enige sodanige werkgewer 'n handeling verrig of versuim om dit te verrig wat 'n misdryf ingevolge hierdie Wet sou wees as die werkgewer dit sou doen of versuim om te doen, kan daardie persoon skuldig bevind en gevonnis word ten opsigte daarvan asof daardie persoon die werkgewer was.

(3) Enige sodanige bestuurder, agent of werknemer kan aldus skuldig bevind en gevonnis word benewens die werkgewer.

HOOFSTUK VI

INSPEKTORAAT

Betreding en deursoeking van persele

40. (1) Die Owerheid moet, vir die behoorlike afdwinging van hierdie Wet, die persone wat hy nodig ag, aanwys as inspekteurs.

(2) Enige persoon wat as 'n inspekteur aangewys is, kan, vir doeleindes van die afdwinging van die bepalings van hierdie Wet en kragtens 'n lasbrief uitgereik ingevolge subartikel (6)—

(a) enige persoon wat daarvan verdink word dat hy of sy enige misdryf ingevolge hierdie Wet pleeg of gepleeg het, deursoek; of

(b) enige—

(i) plek of perseel betree en deursoek van waar 'n persoon wat kragtens hierdie Wet gemagtig is om medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stowwe toe te berei en te resepteer of van waar 'n houer van 'n registrasiesertifikaat soos in artikel 24 beoog, sake doen, indien daar vermoed word dat 'n misdryf ingevolge hierdie Wet gepleeg word; of

(ii) plek, perseel, voertuig, vaartuig of vliegtuig betree en deursoek indien die inspekteur rede het om te vermoed dat 'n misdryf ingevolge hierdie Wet in of op sodanige plek, perseel, voertuig, vaartuig of vliegtuig gepleeg is of word of dat 'n poging aangewend is of word om sodanige misdryf daar te pleeg.

(3) Die betreding en deursoeking van enige persoon, plek, perseel, voertuig, vaartuig of vliegtuig ingevolge hierdie artikel moet geskied met streng inagneming van ordentlikheid en orde, insluitende die beskerming van 'n persoon se reg op—

(a) respek vir sy of haar waardigheid;

(b) vryheid en sekuriteit; en

(c) sy of haar privaatheid.

(4) 'n Inspekteur in artikel (1) beoog, kan, behoudens die bepalings van hierdie artikel—

(a) die onderhawige persoon, plek, perseel, voertuig, vaartuig of vliegtuig

(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 the 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 by 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.

(b) 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.

inspekteer en deursoek en daar sodanige navrae doen as wat die inspekteur nodig ag;

(b) enige medisyne, komplementêre medisyne, veterinêre medisyne, toestel, artikel of dokument wat by of op die persoon, plek, perseel, voertuig, vaartuig of vliegtuig gevind word, ondersoek;

(c) inligting rakende sodanige medisyne, komplementêre medisyne, veterinêre medisyne, toestel, artikel of dokument versoek van die eienaar of persoon in beheer of agent van 'n persoon in beheer van die plek, perseel, voertuig, vaartuig of vliegtuig of van enige persoon in wie se besit of beheer daardie medisyne, komplementêre medisyne, veterinêre medisyne, toestel, artikel of dokument is of van wie daar redelikerwys verwag kan word dat hy of sy die nodige inligting het;

(d) afskrifte maak van of uittreksels maak uit enige sodanige dokument wat op of aan die persoon, plek, perseel, voertuig, vaartuig of vliegtuig gekry is;

(e) beslag lê op enigiets aan of op die persoon, plek, perseel, voertuig, vaartuig of vliegtuig wat op die ondersoek betrekking het;

(f) indien die inspekteur enigiets in paragraaf *(e)* beoog wil behou vir verdere ondersoek of veilige bewaring, dit van die persoon, plek, perseel, voertuig, vaartuig of vliegtuig verwyder met die uitreiking van 'n kwitansie, maar enige medisyne, komplementêre medisyne, veterinêre medisyne, toestel, artikel of dokument wat aldus verwyder is, moet so gou moontlik terugbesorg word nadat die doel waarvoor dit verwyder is, bereik is, en voorts indien daar niemand teenwoordig is om die kwitansie te ontvang wanneer dit uitgereik word nie, moet dit op 'n prominente plek op sodanige plek, perseel, voertuig, vaartuig of vliegtuig aangebring word.

(5) Enige persoon van wie inligting verlang word ingevolge subartikel (4)*(a)* en *(c)*, kan deur 'n regsverteenwoordiger bygestaan word om die inligting te verstrek en moet aldus ingelig word voordat daar van hom of haar verlang word om sodanige inligting te verstrek.

(6) *(a)* 'n Lasbrief in subartikel (2) bedoel, mag net deur 'n landdros of regter van die Hoë Hof in kamers uitgereik word, indien dit vir sodanige landdros of regter uit inligting onder eed blyk dat daar redelike gronde is om te vermoed dat enige medisyne, artikel of dokument wat op die ondersoek betrekking het, in die besit of onder die beheer is van 'n persoon of op 'n plek, perseel, voertuig, vaartuig of vliegtuig geleë binne die regsgebied van sodanige landdros of regter en nie op 'n ander wyse redelikerwys verkry kan word nie.

(b) 'n Lasbrief in subartikel (2) bedoel, moet in die dag uitgevoer word, tensy die persoon wat dit gemagtig het, die uitvoering daarvan in die nag magtig, op tye wat redelik is.

(c) 'n Lasbrief in subartikel (2) bedoel, kan op enige dag uitgereik word en bly van krag totdat—

(i) dit uitgevoer is; of

(ii) dit ingetrek word deur die persoon wat dit uitgereik het of, indien sodanige persoon nie beskikbaar is nie, deur 'n persoon met soortgelyke gesag; of

(iii) een maand verloop het sedert die dag van uitreiking daarvan,

wat ook al eerste gebeur.

(d) 'n Persoon wat 'n lasbrief ingevolge hierdie artikel uitvoer, moet by die aanvang van sodanige deursoeking 'n afskrif van die lasbrief oorhandig aan die persoon in die lasbrief bedoel of die eienaar of die persoon in beheer of die agent of die persoon in beheer van die plek, perseel, voertuig, vaartuig of vliegtuig, indien sodanige persoon aanwesig is, maar indien sodanige persoon nie aanwesig is nie, moet hy of sy 'n afskrif van die lasbrief op 'n opvallende en sigbare plek aan die plek, perseel, voertuig, vaartuig of vliegtuig aanbring.

(e) 'n Persoon wat 'n lasbrief ingevolge hierdie artikel uitvoer, moet hom of haar by die aanvang van sodanige uitvoering identifiseer, en indien die eienaar of die persoon in beheer of die agent van die persoon in beheer van die plek, perseel, voertuig, vaartuig of vliegtuig magtiging vir die uitvoering van 'n lasbrief ingevolge hierdie artikel verlang, moet die besonderhede van sodanige magtiging ook verstrek word.

(7) *(a)* 'n Persoon wat 'n plek, perseel, voertuig, vaartuig of vliegtuig wettig ingevolge hierdie artikel mag betree en deursoek, kan sodanige geweld gebruik as wat nodig is om enige weerstand teen sodanige betreding en deursoeking van die plek, perseel, voertuig, vaartuig of vliegtuig te oorkom, insluitende die breek van enige deur of venster van sodanige plek, perseel, voertuig, vaartuig of vliegtuig.

(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 State 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).

(11) 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) 'n Persoon in paragraaf *(a)* bedoel, moet eers hoorbaar toegang tot die perseel eis en die doel bekend maak waarvoor daardie persoon sodanige plek, perseel, voertuig, vaartuig of vliegtuig wil betree.

(c) Paragraaf *(a)* is nie van toepassing nie waar die betrokke persoon op redelike gronde van mening is dat enige medisyne, komplementêre medisyne, veterinêre medisyne, toestel, artikel of dokument wat die onderwerp van die deursoeking is, vernietig of weggedoen kan word of dat daarmee gepeuter kan word indien daar aan die bepalings van paragraaf *(b)* voldoen word.

(8) Indien tydens die uitvoering van 'n lasbrief ingevolge subartikel (6) 'n persoon daarop aanspraak maak dat 'n artikel of dokument wat aan of op die persoon, plek, perseel, voertuig, vaartuig of vliegtuig gevind is, geprivilegieerde inligting bevat en weier om sodanige artikel of dokument te laat inspekteer, kan die persoon wat die lasbrief uitvoer, die griffier van die Hoë Hof wat jurisdiksie het of daardie griffier se gedelegeerde versoek om op daardie artikel of dokument beslag te lê en dit te verwyder vir veilige bewaring totdat 'n bevoegde hof uitspraak gelewer het oor die vraag of die onderhawige inligting geprivilegieerd is al dan nie.

(9) Indien tydens die uitvoering van 'n lasbrief ingevolge subartikel (6) dit nodig is om geweld te gebruik ten einde toegang te verkry tot 'n plek, perseel, voertuig, vaartuig of vliegtuig soos in subartikel (7)*(a)* beoog en die geweld van sodanige betreding skade veroorsaak aan enige slot, deur, venster, muur of ander deel van sodanige plek, perseel, voertuig, vaartuig of vliegtuig of aan enigiets in sodanige plek, perseel, voertuig, vaartuig of vliegtuig, kan die Owerheid die Minister versoek om magtiging te verleen dat sodanige skade uit Staatsfondse goedgemaak word, maar geen sodanige versoek mag deur die Owerheid gerig en magtiging mag deur die Minister verleen word nie indien die persoon verantwoordelik vir die plek, perseel, voertuig, vaartuig of vliegtuig teenwoordig was ten tyde van betreding en sonder grondige rede versuim het om die betreding te fasiliteer.

(10) Behoudens subartikel (11) kan 'n inspekteur gedurende die dag sonder 'n lasbrief enige plek, perseel, voertuig, vaartuig of vliegtuig betree en deursoek nadat hy of sy homself of haarself geïdentifiseer het, en die bevoegdhede beoog in paragrawe *(a)* en *(b)* van subartikel (2) en subartikel (4) (uitgesonderd die bevoegdheid om enige persoon te deursoek) uitoefen indien—

(a) die bevoegde persoon instem tot sodanige betreding en deursoeking; of

(b) die inspekteur op redelike gronde vermoed dat—

(i) die verlangde lasbrief ingevolge hierdie artikel aan hom of haar uitgereik sal word indien hy of sy daarom sou aansoek doen; en

(ii) die vertraging wat meegebring sou word deur eers die lasbrief te verkry, die oogmerk of doel van die bevoegdhede in paragrawe *(a)* en *(b)* van subartikel (2) of subartikel (4) sal verydel.

(11) Subartikel (10)*(b)* verleen nie magtiging vir, en mag nie toegepas word vir die doel van, die betreding en deursoeking van 'n private woning nie.

(12) Geen antwoord of verklaring gegee deur enige persoon aan 'n inspekteur wat die bevoegdhede uitoefen van die inspekteur ingevolge paragrawe *(a)* en *(c)* van subartikel (4) of gegee of verleen aan enige inspekteur wat soortgelyke bevoegdhede kragtens subartikel (10) uitoefen, indien dit selfinkriminerend is, is toelaatbaar as getuienis teen daardie persoon in strafregtelike verrigtinge wat in enige hof teen hom of haar ingestel word nie.

(13) Die bepalings van subartikel (3) rakende die wyse waarop so 'n deursoeking gedoen moet word, en subartikels (7)*(a)* en *(b)*, (8) en (9) is *mutatis mutandis* van toepassing op 'n inspekteur wat kragtens subartikel (10) optree.

(14) Ondanks subartikel (2) kan 'n inspekteur sonder 'n lasbrief gedurende besigheidsure 'n roetine inspeksie van enige plek of perseel uitvoer vanwaar 'n persoon wat kragtens hierdie Wet gemagtig is om enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, mediese toestel of gelyste stof, te vervaardig, toe te berei, te resepteer, te versprei, te adverteer of te verkoop, besigheid bedryf ten einde nakoming van enige voorgeskrewe vereistes te verseker.

Misdrywe

41. Enige persoon wat—

(a) enige inspekteur in die uitoefening van sy of haar bevoegdhede of die uitvoering van sy of haar pligte ingevolge hierdie Wet dwarsboom of hinder; of

(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

(b) die bepalings van artikel 28 of artikel 33(1) oortree of versuim om daaraan te voldoen; of

(c) die bepalings van artikel 27 oortree of versuim om te voldoen aan 'n kennisgewing kragtens daardie artikel uitgereik; of

(d) artikel 29(1) oortree; of

(e) enige voorwaarde wat kragtens artikel 24(6) gestel is, oortree of versuim om daaraan te voldoen; of

(f) versuim om te voldoen aan enige opdrag gegee kragtens artikel 36 of subartikel (3) van daardie artikel oortree; of

(g) met bedrieglike oogmerke peuter met enige monster wat ingevolge hierdie Wet geneem is; of

(h) enige vals of misleidende verklaring maak in verband met enige medisyne, komplementêre medisyne, veterinêre medisyne, mediese toestel of gelyste stof—

(i) in 'n aansoek om die registrasie daarvan; of

(ii) in die loop van die verkoop daarvan; of

(i) enige medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stof op die houer waarvan 'n vals of misleidende verklaring in verband met die inhoud daarvan geskryf is, verkoop; of

(j) vir doeleindes van 'n besigheid of handel gebruik maak van enige verslag of sertifikaat opgestel of uitgereik deur 'n inspekteur, ontleder, farmakoloog of patoloog ingevolge hierdie Wet; of

(k) artikel 31 oortree of versuim om te voldoen aan enige voorwaarde wat daarkragtens gestel is; of

(l) artikel 45 oortree of versuim om daaraan te voldoen,

is skuldig aan 'n misdryf.

Strawwe

42. (1) Enige persoon wat skuldig bevind word aan 'n misdryf in artikel 41 bedoel, is strafbaar met 'n boete of met gevangenisstraf van hoogstens 10 jaar.

(2) Die hof wat enige persoon skuldig bevind aan 'n misdryf ingevolge hierdie Wet, kan op aansoek van die aanklaer verklaar dat enige medisyne, komplementêre medisyne, veterinêre medisyne, mediese toestel of gelyste stof ten opsigte waarvan die misdryf gepleeg is, aan die Staat verbeur word.

(3) Enige medisyne, komplementêre medisyne, veterinêre medisyne, mediese toestel of gelyste stof wat ingevolge hierdie Wet verbeur word, moet vernietig word of andersins hanteer word soos wat die Owerheid gelas.

(4) Ondanks enige andersluidende bepaling in enige wet is 'n landdroshof bevoeg om enige straf op te lê waarvoor daar in hierdie artikel voorsiening gemaak word.

Vermoedens en bewyslewering

43. (1) In enige strafregtelike verrigtinge ingevolge hierdie Wet—

(a) moet enige hoeveelheid van 'n medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stof in of op enige perseel, plek, voertuig, vaartuig of vliegtuig ten tyde van die neem van 'n monster daarvan ingevolge die bepalings van hierdie Wet, geag word dieselfde eienskappe as sodanige monster te hê, tensy die teendeel bewys word;

(b) moet 'n sertifikaat waarin die resultaat vermeld word van 'n toets, ondersoek of ontleding gedoen ingevolge die bepalings van artikel 40 en wat heet onderteken te wees deur die ontleder, farmakoloog of patoloog wat sodanige toets, ondersoek of ontleding gedoen het, aanvaar word as *prima facie*-bewys van die feite daarin gestel;

(c) moet enige verklaring of inskrywing in enige boek, rekord of dokument wat gehou word deur enige eienaar van 'n medisyne, komplementêre medisyne, veterinêre medisyne, mediese toestel of gelyste stof of deur die bestuurder, agent of werknemer van sodanige eienaar of wat gevind word op of in enige perseel geokkupeer deur of enige voertuig gebruik in die besigheid van sodanige eienaar, toelaatbaar wees in getuienis teen daardie persoon as 'n erkenning van die feite in daardie verklaring of inskrywing uiteengesit, tensy daar bewys word dat die verklaring of inskrywing nie deur sodanige eienaar of deur enige bestuurder, agent of werknemer van sodanige eienaar in die

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 VII

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 except 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 competent jurisdiction, disclose to any person any information in relation to the acquisition, supply, marketing, importation, export, development, manufacture, or research in connection 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 section 31(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 internationally, 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 period 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 fit.

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

loop van sy of haar werk as bestuurder of in die loop van sy of haar agentskap of diens gedoen is nie.

(2) Die hof waar enige sodanige sertifikaat voorgelê word in getuienis, kan na goeddunke die persoon wat sodanige sertifikaat geteken het, laat dagvaar om mondelinge getuienis te lewer in die onderhawige verrigtinge of kan skriftelike vraagpunte aan daardie persoon laat voorlê vir beantwoording, en sodanige vraagpunte en enige antwoord daarop wat 'n antwoord van sodanige persoon heet te wees, is aanvaarbaar in getuienis in sodanige verrigtinge.

HOOFSTUK VII

ONTBINDING VAN OWERHEID, VERBOD OP OPENBAARMAKING VAN SEKERE INLIGTING, REGULASIES, HERROEPING EN WYSIGING VAN SEKERE ARTIKELS VAN WET 101 VAN 1965 EN WET 36 VAN 1947, EN VOORBEHOUDSBEPALINGS

Ontbinding van Owerheid

44. Die Owerheid mag slegs by of op gesag van 'n Wet van die Parlement ontbind word.

Verbod op openbaarmaking van sekere inligting

45. (1) Geen persoon wat 'n lid van die Raad, die personeel van die Owerheid of komitees van die Owerheid is of enige diens aan die Owerheid lewer, mag, behalwe soos vereis by 'n bevel uitgereik deur 'n bevoegde hof, aan enige persoon enige inligting openbaar maak nie met betrekking tot die verkryging, verskaffing, bemarking, invoer, uitvoer, ontwikkeling, vervaardiging of navorsing in verband met enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of mediese toestel, preparaat of enige ander aangeleentheid wat daarmee verband hou, deur enige aansoeker.

(2) Subartikel (1) verhinder nie die openbaarmaking van inligting—

(a) van besluite van die Raad in ooreenstemming met sy reëls nie;

(b) waar die Raad van mening is dat die openbaarmaking in belang van openbare gesondheid sal wees nie;

(c) deur enige lid van die Owerheid in ooreenstemming met die bepalings van die nasionale wetgewing beoog in artikel 31(2) van die Grondwet nie;

(d) wat vrygestel is vir publikasie deur die Minister of deur 'n persoon wat deur die Minister daartoe gemagtig is nie, in die belang van openbare gesondheid;

(e) aan ander nasionale of internasionale agentskappe nie, indien dit in ooreenstemming is met die oogmerke van die Owerheid en nodig is vir die verrigting van die funksies van die Owerheid.

(3) Enige persoon wat subartikel (1) oortree, is skuldig aan 'n misdryf en is by skuldigbevinding strafbaar met 'n boete of met gevangenisstraf vir 'n tydperk van hoogstens 12 maande of met sowel sodanige boete as sodanige gevangenisstraf.

Verrigtinge deur Minister in die geval van nie-nakoming van Wet deur Owerheid

46. (1) Indien dit te eniger tyd vir die Minister blyk dat die Owerheid versuim om enige van die vereistes van hierdie Wet na te kom, kan die Minister by skriftelike kennisgewing van die Owerheid vereis om die versuim binne 'n bepaalde tyd reg te stel.

(2) Indien die Owerheid versuim om aan die bepalings van sodanige kennisgewing te voldoen, kan die Minister by 'n bevoegde hof aansoek doen om 'n bevel wat die Owerheid verplig om die versuim reg te stel, en die hof kan sodanige bevel daaroor maak as wat hy goedvind.

Beperking van aanspreeklikheid

47. Geen regsverrigtinge kan teen enige lid van die Owerheid, sy komitees of enige persoon wat in enige van sy komitees gekoöpteer is of enige persoon wat deur die Owerheid gekontrakteer is om hom met die verrigting van sy funksies ingevolge hierdie Wet by te staan, ingestel word nie ten opsigte van enige handeling wat te goeder trou verrig is deur enige lid van die Owerheid, sy komitees of enige persoon wat in enige van sodanige komitees gekoöpteer is of enige persoon wat deur die Owerheid

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(1);

(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

gekontrakteer is om hom met die verrigting van sy funksies ingevolge hierdie Wet by te staan.

Regulasies

48. (1) Die Minister kan, in oorleg met die Owerheid, regulasies uitvaardig wat nie met hierdie Wet onbestaanbaar is nie—

(a) rakende die kategorieë persone deur wie aansoek gedoen kan word om die registrasie van enige ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of toestel of aan wie 'n registrasiesertifikaat oorgedra kan word;

(b) rakende die vorms wat gebruik moet word vir enige aansoek om die registrasie van enige medisyne en die besonderhede wat met enige sodanige aansoek verstrek moet word (insluitende besonderhede rakende die metode waarvolgens die onderhawige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of enige komponent van sodanige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne vervaardig word en die perseel waar sodanige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of enige sodanige komponent vervaardig word);

(c) om voorsiening te maak vir die klassifisering van ortodokse medisyne, komplementêre medisyne of veterinêre medisyne in klasse of kategorieë vir doeleindes van hierdie Wet;

(d) rakende die monsters van enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne en die hoeveelheid daarvan wat enige aansoek om die registrasie van sodanige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne moet vergesel;

(e) rakende die vorm waarin die register in artikel 24(5) bedoel, gehou moet word en die besonderhede wat daarin aangeteken moet word ten opsigte van enige geregistreerde ortodokse medisyne, komplementêre medisyne of veterinêre medisyne;

(f) rakende die vorm van enige registrasiesertifikaat van enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne;

(g) rakende die omstandighede waarin, die voorwaardes waarop en die persoon of kategorieë persone aan wie enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of gelyste stof verkoop mag word;

(h) rakende die wyse waarop enige verpakking wat enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of gelyste stof geëtiketteer, verpak of verseël moet word;

(i) rakende die besonderhede met betrekking tot die gebruik daarvan wat verskaf moet word met enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of gelyste stof wat verkoop word, en die wyse waarop sodanige besonderhede verstrek moet word;

(j) rakende die besonderhede wat in enige advertensie rakende enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of gelyste stof moet verskyn, of om die insluiting van enige bepaalde besonderhede in sodanige advertensie, of die verspreiding van enige sodanige advertensie aan 'n bepaalde persoon of 'n bepaalde kategorie persone of aan 'n bepaalde organisasie of 'n bepaalde kategorie organisasies te verbied;

(k) rakende die vereistes waaraan enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of enige komponent daarvan moet voldoen met betrekking tot samestelling, terapeutiese geskiktheid en effek, suiwerheid of enige ander eienskap;

(l) rakende die besonderhede wat in die *Staatskoerant* gepubliseer moet word met betrekking tot enige aansoek om registrasie in artikel 24(1) bedoel;

(m) rakende die besonderhede wat moet verskyn op 'n voorskrif of op 'n bestelling vir 'n ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stof, die getal uitreikings van 'n ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stof wat op enige sodanige bepaalde voorskrif of bestelling gedoen kan word, die wyse waarop enige sodanige voorskrif of bestelling uitgereik moet word en die tydperk waarvoor enige sodanige voorskrif of bestelling behou moet word;

(n) rakende die vorm van lisensies, registers, voorskrifboeke, rekords en ander dokumente wat gehou of gebruik moet word ten opsigte van gelyste stowwe,

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

(u) authorising 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) authorising, 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

die wyse waarop dit gehou moet word, die besonderhede wat daarin aangeteken moet word en die plek waar en die tydperk waartydens dit behou moet word;

(o) om die voorlegging te vereis van opgawes, verslae en inligting ten opsigte van gelyste stowwe en plante waaruit enige sodanige stof geëkstraheer, afgelei, geproduseer of vervaardig kan word, en ten opsigte van enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of ander stof waarvan enige sodanige gelyste stof 'n komponent is;

(p) rakende die oorlaai of die uitvoer uit of invoer in die Republiek van enige gelyste stof, met vermelding van die hawens of plekke waar sodanige stof die Repliek ingebring kan word;

(q) om die versending na die Republiek van gelyste stowwe te magtig en te reguleer of te beperk;

(r) rakende die wyse waarop verpakkings bevattende gelyste stowwe geëtiketteer moet word wanneer dit na die Republiek ingevoer of in die Republiek vervaardig word en die persone deur wie en die wyse waarop dit gehou moet word;

(s) om die aankoop, verkryging, hou of gebruik van preparate van kokaïen deur bestuurders of persone in beheer van fabrieke of werkwinkels in verband met die behandeling van oogbeserings of vir ander noodsaaklike doeleindes te magtig en te reguleer;

(t) om die aankoop, verkryging, hou of gebruik van gelyste stowwe deur bepaalde persone of kategorieë persone te magtig en te reguleer;

(u) om die besit deur persone wat die Republiek binnekom of verlaat van bepaalde hoeveelhede gelyste stowwe vir persoonlike medisinale gebruik te magtig en te reguleer;

(v) rakende die beskikking oor of vernietiging van 'n ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of 'n gelyste stof, en die rekords wat ten opsigte daarvan gehou moet word;

(w) rakende die invoer, vervoer, hou, berging, verwerking en verpakking van ortodokse medisyne, komplementêre medisyne, veterinêre medisyne en gelyste stowwe, en die wyse waarop ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, toestelle en gelyste stowwe gehou en beheer moet word in verskillende kategorieë hospitale;

(x) om die metode waarvolgens monsters ingevolge hierdie Wet geneem kan word en die vorm van die sertifikate wat deur inspekteurs ten opsigte van sulke monsters uitgereik moet word, voor te skryf;

(y) om die metodes wat gebruik moet word en die vorm van die sertifikate wat uitgereik moet word in verband met die toets, ondersoek of ontleding van monsters wat ingevolge hierdie Wet geneem is, voor te skryf;

(z) om die registrasie, vervaardiging, modifikasie, invoer, berging, vervoer, verkoop of gebruik van enige mediese toestel of klas mediese toestelle of ortodokse medisyne, komplementêre medisyne of veterinêre medisyne ten opsigte van die veiligheid, gehalte en doeltreffendheid daarvan te magtig, te reguleer, te beheer, te beperk of te verbied;

(zA) met betrekking tot enige aangeleentheid om die veiligheid, gehalte en doeltreffendheid van ortodokse medisyne, komplementêre medisyne of veterinêre medisyne en mediese toestelle te verseker;

(zB) rakende die summiere beslaglegging op en beskikking oor enige gelyste stof wat in die besit of bewaring gekry is van enige persoon wat nie ingevolge hierdie Wet geregtig is om dit te hou of te gebruik nie;

(zC) rakende die beskikking oor of vernietiging van 'n gelyste stof wat ongeskik vir gebruik geword het, en die verslag wat ten opsigte daarvan gelewer moet word;

(zD) rakende die gelde wat aan die Owerheid betaal moet word ten opsigte van 'n aansoek om die registrasie, en ten opsigte van die registrasie van 'n ortodokse medisyne, komplementêre medisyne of veterinêre medisyne, gelyste stof of mediese toestel, die geld wat jaarliks aan die Owerheid betaal moet word ten opsigte van die behoud van die registrasie van 'n ortodokse medisyne, komplementêre medisyne of veterinêre medisyne, gelyste stof of mediese toestel en die datum waarop sodanige jaarlikse geld betaal moet word;

(zE) rakende die gelde betaalbaar ten opsigte van die magtiging van die gebruik van ongeregistreerde ortodokse medisyne, komplementêre medisyne of

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 medicines 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, complementary 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 *(zE)* 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.

veterinêre medisyne, die uitreiking of hernuwing van enige lisensie ingevolge hierdie Wet, die doen van inspeksies om die gehalte van ortodokse medisyne, komplementêre medisyne, veterinêre medisyne, gelyste stowwe of mediese toestelle te bepaal vir doeleindes van registrasie en die evaluering van veranderinge aan die besonderhede vervat in registers;

(zF) rakende appèlle teen besluite van die Direkteur-generaal of die Owerheid;

(zG) rakende die voorwaardes waarop ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stowwe verkoop mag word;

(zH) rakende die herverpakking van ortodokse medisyne, komplementêre medisyne of veterinêre medisyne in pakke gereed vir gebruik deur pasiënte;

(zI) rakende die wetenskaplike, farmaseutiese, kliniese en ander vaardighede wat vereis word deur lede van die Owerheid of deur 'n lid van die Uitvoerende Komitee van die Owerheid om die veiligheid, gehalte en doeltreffendheid van ortodokse medisyne, komplementêre medisyne, mediese toestel of veterinêre medisyne te evalueer;

(zJ) rakende die veiligheid, gehalte en doeltreffendheid van ingevoerde ortodokse medisyne, komplementêre medisyne of veterinêre medisyne;

(zK) rakende die beheer oor en doen van kliniese proewe; en

(zL) enige ander aangeleentheid wat nie met hierdie Wet onbestaanbaar is nie.

(2) Die Minister moet, ten minste drie maande voordat enige regulasie kragtens subartikel (1) uitgevaardig word, die teks van sodanige regulasie in die *Staatskoerant* laat publiseer, tesame met 'n kennisgewing bevattende die Minister se voorneme om daardie regulasie uit te vaardig en waarin belanghebbende persone uitgenooi word om die Minister te voorsien van kommentaar daarop of enige vertoë wat hulle in verband daarmee wil rig.

(3) Subartikel (3) is nie van toepassing nie ten opsigte van—

(a) enige regulasie wat, nadat daar aan daardie subartikel voldoen is, deur die Minister gewysig is as gevolg van kommentaar of vertoë wat deur die Minister ontvang is voortspruitend uit die kennisgewing wat daarkragtens uitgereik is;

(b) enige regulasie ten opsigte waarvan die Minister, na oorleg met die Owerheid, van mening is dat dit in openbare belang sonder versuim uitgevaardig moet word.

(4) 'n Regulasie kragtens subartikel (1)(zD) en (zE) moet slegs in oorleg met die Minister van Finansies uitgevaardig word.

(5) Regulasies uitgevaardig kragtens subartikel (1)*(k)* kan voorskryf dat enige ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of enige komponent daarvan moet voldoen aan die vereistes uiteengesit in enige publikasie wat na die mening van die Owerheid algemeen as gesaghebbend erken word.

(6) Regulasies kan kragtens hierdie artikel uitgevaardig word ten opsigte van bepaalde ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stowwe of klasse of kategorieë ortodokse medisyne, komplementêre medisyne of veterinêre medisyne of gelyste stowwe, of ten opsigte van ander ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stowwe as bepaalde klasse of kategorieë ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stowwe, en verskillende regulasies kan aldus uitgevaardig word ten opsigte van verskillende ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stowwe of verskillende klasse of kategorieë ortodokse medisyne, komplementêre medisyne, veterinêre medisyne of gelyste stowwe.

(7) Regulasies wat kragtens hierdie artikel uitgevaardig word, kan strawwe van 'n boete of gevangenisstraf, maar hoogstens die maksimum straf waarvoor daar in artikel 42 voorsiening gemaak word, voorskryf vir enige oortreding daarvan of versuim om daaraan te voldoen.

(8) Ondanks die bepalings van subartikel (1) kan die Minister, indien die Minister dit in openbare belang ag, na oorleg met die Raad of die Uitvoerende Komitee daarvan, regulasies uitvaardig met betrekking tot enige aangeleentheid in subartikel (1) bedoel.

Wet bind die Staat

49. Hierdie Wet bind die Staat.

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), specified 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 done 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), 1978, 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 performing 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, 1971 (Act No 21 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.

Herroeping en wysiging van sekere artikels, en voorbehoudsbepalings

50. (1) Behoudens subartikel (2) word—

(a) die wette in Bylae 1 vermeld, word hierby herroep in die mate in daardie Bylae aangedui; en

(b) die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947 (Wet No. 36 van 1947), vermeld in Bylae 2 word hierby gewysig in die mate in daardie Bylae aangedui.

(2) By die inwerkingtreding van hierdie Wet—

(a) moet enigiets wat voor die inwerkingtreding van hierdie Wet gedoen is ingevolge die herroepe Wet op die Beheer van Medisyne en Verwante Stowwe, 1965, en die Medicines and Related Substances Control Act (Transkei), 1978, en die gewysigde bepalings van die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947, ten opsigte van veemiddels, geag word ingevolge hierdie Wet gedoen te wees;

(b) moet permitte, lisensies of sertifikate wat voor sodanige inwerkingtreding uitgereik is deur die Medisynebeheerraad of enige liggaam ingevolge die bepalings van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965, of deur enige liggaam ingevolge die Medicines and Related Substances Control Act (Transkei), 1978, geag word permitte, lisensies of registrasiesertifikate te wees wat ingevolge hierdie Wet deur die Owerheid uitgereik is; en

(c) moet permitte, lisensies of registrasiesertifikate wat voor sodanige inwerkingtreding uitgereik is ingevolge die Wet op Misstowwe, Veevoedsel, Landboumiddels en Veemiddels, 1947, ten opsigte van veemiddels, geag word permitte, lisensies of registrasiesertifikate ten opsigte van veterinêre medisyne te wees wat ingevolge hierdie Wet deur die Owerheid uitgereik is.

(3) Behoudens hierdie Wet moet die Registrateur ingevolge die Medisynewet aangestel as die Hoof- Uitvoerende Beampte optree tot 'n dag direk voor die dag waarop 'n Hoof- Uitvoerende Beampte ingevolge artikel 16 aangestel is.

(4) Behoudens hierdie Wet, moet die Medisynebeheerraad by artikel 2 van die Medisynewet ingestel die funksies van die Raad verrig tot 'n dag direk voor die dag waarop die Minister die raad ingevolge artikel 6 aanstel.

(5) 'n Beampte of werknemer van—

(a) die Departement van Gesondheid se Direktoraat: Medisyne-administrasie wat ondersteuning aan die bedoelde Medisynebeheerraad verskaf, kan as 'n personeellid van die Owerheid optree tot op 'n datum wat die Direkteur-generaal van Gesondheid bepaal; en

(b) die Departement van Landbou wat op 'n voltydse basis funksies betreffende veemiddele verrig, kan as 'n personeellid van die Owerheid optree tot op 'n datum wat die Direkteur-generaal van Gesondheid, handelende in oorleg met die Direkteur-generaal van Landbou, bepaal.

Herroeping van sekere wette

51. Alle wette wat deel uitgemaak het van die wetgewing van die Republieke van Transkei, Bophuthatswana, Venda en Ciskei en die wette wat deel uitgemaak het van die wetgewing van die selfregerende gebiede van Lebowa, Gazankulu, Qwaqwa, KwaZulu, KwaNdebele en KaNgwane ingevolge die Grondwet van die Nasionale State, 1971 (Wet No. 21 van 1971), in die mate dat dit handel oor aangeleenthede waarvoor daar in hierdie Wet voorsiening gemaak word, moet geag word herroep te wees.

Werking van Wet met betrekking tot ander wette

52. Hierdie Wet geld benewens en nie ter vervanging nie van enige ander wet wat nie strydig of onbestaanbaar met hierdie Wet is nie.

Voortsetting van bestaande regulasies en bylaes van stowwe ingevolge die Medisynewet

53. (1) Behoudens hierdie Wet moet alle regulasies uitgevaardig kragtens die Medisynewet en enige bylaes van stowwe wat vasgestel is ingevolge die Medisynewet voortbestaan, behoudens enige herroeping of wysiging deur 'n bevoegde owerheid.

(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*.

(2) Behoudens hierdie Wet moet alle regulasies uitgevaardig kragtens die Veemiddelswet en enige bylaes wat vasgestel is ingevolge die Veemiddelswet ten opsigte van veemiddels voortbestaan, behoudens enige herroeping of wysiging deur 'n bevoegde owerheid.

(3) Ondanks subartikel (1) maar behoudens subartikel (4) word Bylae 1 tot en met Bylae 9 van die Medisynewet hierby herroep.

(4) Enige verwysing in enige wet of dokument na enige medisyne of stof in enige bylae van die Medisynewet bedoel voor die datum van inwerkingtreding van hierdie Wet, moet vanaf daardie datum uitgelê word as 'n verwysing na die ooreenstemmende medisyne of ander stof wat kragtens artikel 31 deur die Minister voorgeskryf is.

Wysiging van bylaes

54. Die Minister kan, op aanbeveling van die Owerheid, by kennisgewing in die *Staatskoerant*, die bylaes in artikel 53 bedoel wysig deur die insluiting daarin of die skrapping daaruit van enige medisyne of ander stof, of op enige ander wyse.

Kort titel en inwerkingtreding

55. Hierdie Wet heet die Wet op die Suid-Afrikaanse Regulerende Owerheid vir Medisyne en Mediese Toestelle, 1998, en tree in werking op 'n datum wat die President by proklamasie in die *Staatskoerant* bepaal.

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.

BYLAE 1

HERROEPING VAN WETTE

(Artikel 50)

No. en jaar van wet	Kort titel	Mate waarin gewysig
Wet No. 101 van 1965	Wet op die Beheer van Medisyne en Verwante Stowwe, 1965	Die geheel, behalwe artikels 1, 15B, 18, 22B, 24, 34A en 40.
Wet No. 90 van 1997	Wysigingswet op die Beheer van Medisyne en Verwante Stowwe, 1997	Die geheel, behalwe artikels 1, 10, 12, 14, 15, 22, 26, 28, 31 en 33.
Wet No. 27 van 1978 (Transkei)	"Medicines and Related Substances Control Act, 1978"	Die geheel.

SCHEDULE 2

No. and year of Law	Short title	Extent of Amendment
Act No. 36 of 1947	Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947	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, advantages or uses 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 **[and 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.** (1) 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) *(a)* 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.

BYLAE 2

No en jaar van wet	Kort titel	Mate waarin gewysig
Wet No. 36 van 1947	Wet op Misstowwe, Veevoedsel, Landboumid-dels en Veemiddels, 1947	Die wysiging van artikel 1 van Wet 36 van 1947, soos gewysig by artikel 1 van Wet 24 van 1947 en artikel 1 van Wet 4 van 1980. 1. Artikel 1 van Wet 36 van 1947 word hierby gewysig— *(a)* deur die omskrywing van "advertensie" deur die volgende omskrywing te vervang: " 'advertensie' enige skriftelike, geïllustreerde, visuele of ander beskrywende stof of mondelinge verklaring, mededeling, voorstelling of verwysing wat onder lede van die publiek versprei of op 'n ander wyse onder hulle aandag gebring word en wat bedoel is om die verkoop van misstowwe, veevoedsel of landboumiddels **[of veemiddels]** te bevorder of die gebruik daarvan aan te moedig of die aandag te vestig op die aard, eienskappe, voordele of gebruike daarvan, en het 'adverteer' 'n ooreenstemmende betekenis;"; *(b)* deur die omskrywing van "aanleg" deur die volgende omskrywing te vervang: " 'aanleg', met betrekking tot 'n misstof, veevoedsel of landboumiddel **[of veemiddel],** die perseel waar sodanige misstof, veevoedsel of landboumiddel **[of veemiddel]** vir die doeleindes van verkoop, vervaardig, beheer, verpak, gemerk of geëtiketteer word;"; *(c)* deur die omskrywing van "registrateur" deur die volgende omskrywing te vervang: " 'registrateur' die Registrateur van Misstowwe, Veevoedsel en Landboumiddels **[en Veemiddels]** ingevolge artikel 2 aangewys, en ook 'n beampte wat in opdrag of onder die beheer of op las van die registrateur optree;".
		Die vervanging van artikel 2 van Wet 36 van 1947, soos gewysig by artikel 2 van Wet 60 van 1970 en vervang by artikel 2 van Wet 24 van 1977. 2. Artikel 2 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Aanwysing van registrateur** 2. (1) Die Minister wys 'n beampte in die Departement van Landbou-tegniese Dienste aan as Registrateur van Misstowwe, Veevoedsel en Landboumiddels **[en Veemiddels]** wat, behoudens die opdragte van die Minister, die bevoegdhede uitoefen, die werksaamhede verrig en die pligte uitvoer wat kragtens hierdie Wet aan die registrateur verleen, toegewys of opgedra word. (2) *(a)* 'n Bevoegdheid verleen of werksaamheid toegewys of plig opgedra aan die registrateur, kan deur 'n beampte in opdrag of onder die beheer of op las van die registrateur uitgeoefen, verrig of uitgevoer word.

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		(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 purpose 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 of 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 remedy]**, sterilizing plant or pest control operator shall be made to the registrar in the prescribed mannerand shall be accompanied by the prescribed application fee. *(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 she 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:

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		(b) 'n Beslissing of opdrag gegee deur so 'n beampte kan deur die registrateur ingetrek of gewysig word, en word, totdat dit aldus ingetrek of gewysig is, behalwe by die toepassing van hierdie paragraaf, geag deur die registrateur gegee te gewees het.".
		Die vervanging van artikel 3 van Wet 36 van 1947, soos gewysig by artikel 3 van Wet 60 van 1970, artikel 3 van Wet 24 van 1977 en artikel 2 van Wet 4 van 1980. 3. Artikel 3 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Registrasie van misstowwe, veevoedsel, landboumiddels, veemiddels, steriliseringsinstallasies en plaagbeheeroperateurs** 3. (1) *(a)* Aansoek om registrasie van 'n misstof, veevoedsel, landboumiddel, **[veemiddel,]** sterliseringsinstallasie of plaagbeheeroperateur moet by die registrateur op die voorgeskrewe wyse gedoen word en vergesel word van die voorgeskrewe aansoekgeld. *(b)* Iemand wat om registrasie ingevolge paragraaf *(a)* aansoek doen, moet die monsters en besonderhede wat die registrateur vereis, aan hom of haar verskaf of tot sy of haar beskikking stel op die wyse, tyd en plek wat hy of sy bepaal. (2) Indien die registrateur na oorweging van so 'n aansoek en na die ondersoek of navraag wat hy of sy nodig ag, oortuig is dat— *(a)* die misstof, veevoedsel of landboumiddel **[of veemiddel]** ten opsigte waarvan om registrasie aansoek gedoen word, geskik en doeltreffend genoeg is vir die oogmerk waarvoor dit bestem is, en aan die voorgeskrewe vereistes voldoen, en dat dit nie strydig met die openbare belang is dat dit geregistreer word nie, en dat die aanleg waar dit vervaardig word, geskik is vir sodanige vervaardiging, moet hy of sy daardie misstof, veevoedsel of landboumiddel **[of veemiddel]** registreer; *(b)* die steriliseringsinstallasie ten opsigte waarvan om registrasie aansoek gedoen word, geskik en doeltreffend genoeg is vir die oogmerk waarvoor dit bestem is, en aan die voorgeskrewe vereistes voldoen, en dat dit nie strydig met die openbare belang is dat daardie steriliseringsinstallasie geregistreer word nie, moet hy of sy daardie steriliseringsinstallasie registreer; *(c)* die plaagbeheeroperateur ten opsigte waarvan om registrasie aansoek gedoen word oor die voorgeskrewe kwalifikasies beskik of andersins, in die mate wat die registrateur bepaal, bedrewe is in die gebruik van landboumiddels, en dat nie strydig met die openbare belang is dat daardie plaagbeheeroperateur geregistreer word nie, moet hy of sy daardie plaagbeheeroperateur registreer:

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		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 a 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 4 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 contra vened 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 and efficacy specified in the application for registration thereof, 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

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		Met dien verstande dat die registrateur 'n aansoek om registrasie van 'n misstof, veevoedsel, landboumiddel, **[veemiddel,]** sterliseringsinstallasie of plaagbeheeroperateur kan weier indien 'n vorige registrasie van so 'n misstof, veevoedsel, landboumiddel, **[veemiddel,]** sterliseringsinstallasie of plaagbeheeroperateur kragtens artikel 4 ingetrek is. (3) 'n Registrasie kragtens hierdie artikel is onderworpe aan die voorgeskrewe en enige bykomende voorwaardes wat die registrateur bepaal en is geldig vir sodanige tydperk as wat voorgeskryf is, en die registrateur moet ten opsigte van sodanige registrasie 'n registrasiesertifikaat uitreik aan die persoon wat daarom aansoek gedoen het. (4) *(a)* 'n Registrasie kragtens hierdie artikel kan by verstryking van die tydperk waarvoor dit geldig is, hernuwe word. *(b)* Die bepalings van subartikels (1), (2) en (3) is *mutatis mutandis* op die hernuwing van 'n registrasie van toepassing.".
		Die vervanging van artikel 4 van Wet 36 van 1947, soos vervang by artikel 4 van Wet 60 van 1970 en artikel 4 van Wet 24 van 1977 en gewysig by artikel 3*(c)* van Wet 4 van 1980. 4. Artikel 4 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Intrekking van registrasie** 4 (1) Die registrateur kan die registrasie van 'n misstof, veevoedsel of landboumiddel **[of veemiddel]** te eniger tyd intrek indien hy of sy oortuig is— *(a)* dat iemand in verband met die betrokke registrasie 'n bepaling van hierdie Wet oortree het of versuim het om daaraan te voldoen; (aA) dat iemand 'n voorwaarde waaraan die betrokke registrasie onderworpe is, oortree het of versuim het om daaraan te voldoen; *(b)* dat sodanige misstof, veevoedsel of landboumiddel **[of veemiddel]** nie so saamgestel en so doeltreffend is as wat in die aansoek om registrasie daarvan gespesifiseer is nie, nie die chemiese, fisiese en ander eienskappe aldus gespesifiseer, besit nie en nie voldoen aan die vereistes wat voorgeskryf is nie; *(c)* dat die praktyke gevolg en fasiliteite beskikbaar by of ten opsigte van die aanleg of die onderneming wat daar bedryf word nie geskik is vir die vervaardiging van die betrokke misstof, veevoedsel of landboumiddel **[of veemiddel]** nie; *(d)* dat die persoon wat so 'n onderneming bestuur nie oor voldoende kennis beskik nie ten opsigte van die betrokke bepalings van hierdie Wet of die praktyke wat gevolg moet word in die bedryf van so 'n onderneming; *(e)* dat dit strydig met die openbare belang is dat sodanige misstof, veevoedsel of landboumiddel **[of veemiddel]** geregistreer bly; of

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		(f) that any incorrect or misleading advertisement is used in connection with such fertilizer, farm feed, or agricultural remedy **[or stock 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 is subject; *(c)* the sterilizing plant does 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 is contrary to the public interest that the sterilizing plant shall remain registered. (3) The registrar may cancel the registration of any pest 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 to 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 whom 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 **[or stock remedy]**, cause that certificate of registration or a copy thereof to be 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 of 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 regis tration shall lapse— *(a)* if the person to whom 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 the establishment in question is no longer used for the manufacture of such fertilizer, farm feed, agricultural remedy or stock feed.

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		(f) dat 'n onjuiste of misleidende advertensie in verband met sodanige misstof, veevoedsel of landboumiddel **[of veemiddel]** gebruik word. (2) Die registrateur kan die registrasie van 'n steriliseringsinstallasie te eniger tyd intrek indien hy of sy oortuig is dat— *(a)* iemand in verband met die betrokke registrasie 'n bepaling van hierdie Wet oortree het of versuim het om daaraan te voldoen; *(b)* iemand 'n voorwaarde waaraan die betrokke registrasie onderworpe is, oortree het of versuim het om daaraan te voldoen; *(c)* die steriliseringsinstallasie nie voldoen aan die voorgeskrewe vereistes nie of andersins nie effektief toegerus is vir die sterilisering van die stowwe bedoel in die omskrywing van 'steriliseringsinstallasie' nie; *(d)* dit strydig met die openbare belang is dat die steriliseringsinstallasie geregistreer bly. (3) Die registrateur kan die registrasie van 'n plaagbeheeroperateur te eniger tyd intrek indien hy of sy oortuig is dat— *(a)* die plaagbeheeroperateur 'n bepaling van hierdie Wet of 'n voorwaarde van sy registrasie oortree het of versuim het om daaraan te voldoen; *(b)* die plaagbeheeroperateur versuim het om te voldoen aan 'n lasgewing uitgereik kragtens artikel 6A; *(c)* dit strydig met die openbare belang is dat die plaagbeheeroperateur geregistreer bly.".
		Die vervanging van artikel 4A van Wet 36 van 1947, soos ingevoeg by artikel 5 van Wet 24 van 1977 en gewysig by artikel 4*(a)* en *(c)* van Wet 4 van 1980. 5. Artikel 4A van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Beskikbaarheid, verval en terugsending van registrasiesertifikaat** 4A. (1) Iemand aan wie 'n registrasiesertifikaat ingevolge artikel 3(3) uitgereik is, moet— *(a)* in die geval van 'n misstof, veevoedsel of landboumiddel **[of veemiddel]** toesien dat daardie registrasiesertifikaat of 'n kopie daarvan te alle tye by die aanleg waar sodanige misstof, veevoedsel of landboumiddel **[of veemiddel]** vervaardig word ter insae deur die registrateur beskikbaar is; of *(b)* in die geval van 'n steriliseringsinstallasie of 'n plaagbeheeroperateur, daardie registrasiesertifikaat of 'n kopie daarvan aan die registrateur toon wanneer hy of sy daarom versoek word. (2) Die registrasie van 'n misstof, veevoedsel of landboumiddel **[of veemiddel]** en die registrasiesertifikaat uitgereik ten opsigte van sodanige registrasie verval—

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		(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. (2B) 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 (2B) 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 substitution 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 of 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 provisions 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

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		(a) indien die persoon aan wie die registrasiesertifikaat uitgereik is, ophou om die betrokke misstof, veevoedsel of landboumiddel of **[veemiddel]** te vervaardig of te verkoop; of *(b)* indien die betrokke aanleg nie langer vir die vervaardiging van die misstof, veevoedsel of landboumiddel **[of veemiddel]** gebruik word nie. (2A) Die registrasie van 'n steriliseringsinstallasie en die registrasiesertifikaat uitgereik ten opsigte van sodanige registrasie verval indien die geregistreerde installasie ophou om as 'n steriliseringsinstallasie gebruik te word. (2B) Die registrasie van 'n plaagbeheeroperateur en die registrasiesertifikaat uitgereik ten opsigte van sodanige registrasie verval indien die geregistreerde persoon ophou om 'n plaagbeheeroperateur te wees. (3) Wanneer die registrasie van enige misstof, veevoedsel, landboumiddel, **[veemiddel,]** steriliseringsinstallasie of plaagbeheeroperateur ingevolge subartikel (2), (2A) of (2B) verval het of ingevolge die bepalings van artikel 4 ingetrek is, moet die betrokke registrasiesertifikaat deur die persoon aan wie dit uitgereik is, binne die voorgeskrewe tydperk aan die registrateur teruggestuur word.".
		Die vervanging van artikel 7 van Wet 36 van 1947, soos vervang by artikel 5 van Wet 60 van 1970 en artikel 8 van Wet 24 van 1977. 6. Artikel 7 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Verkoop van misstowwe, veevoedsel, landboumiddels en veemiddels** 7. (1) Niemand mag 'n misstof, veevoedsel of landboumiddel **[en veemiddel]** verkoop nie tensy— *(a)* dit kragtens hierdie Wet geregistreer is onder die naam of merk waaronder dit aldus verkoop word: Met dien verstande dat 'n misstof, veevoedsel of landboumiddel **[en veemiddel]** ten opsigte waarvan die geldigheidsduur van die registrasie verstryk het, die registrasiesertifikaat ingevolge artikel 4 ingetrek is of ingevolge artikel 4A(2) verval het, en wat voor of op die datum van sodanige intrekking of verval nie meer onder die beheer of besit is van die persoon aan wie daardie registrasiesertifikaat uitgereik was nie, behoudens die bepalings van artikel 7*bis* verkoop mag word; *(b)* dit, behoudens die bepalings van paragraaf *(c)*, verpak is op sodanige wyse en in sodanige massa of volume as wat voorgeskryf mag word; *(c)* die houer waarin dit verkoop word, voldoen aan die voorgeskrewe vereistes en verseël en geëtiketteer of gemerk is op so 'n wyse as wat voorgeskryf mag word of, indien dit nie in 'n houer verkoop word nie, dit deur die in artikel 9 bedoelde faktuur vergesel word; en

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		(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 or agricultural remedy **[or stock remedy]** for a purpose or in a 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 veterinar ian 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 48 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."

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		(d) dit so saamgestel en so doeltreffend is as wat in die aansoek om registrasie daarvan gespesifiseer is, alle chemiese, fisiese en ander eienskappe aldus gespesifiseer, besit en aan die voorgeskrewe vereistes voldoen. (2) *(a)* Niemand mag teen vergoeding of in die loop van 'n bedryf, handel of besigheid— (i) 'n landboumiddel **[of veemiddel]** gebruik, of die gebruik daarvan aanbeveel, vir 'n ander doel of op 'n ander wyse as dié wat aangedui word op die etiket op die houer daarvan of as wat op sodanige houer gespesifiseer word nie; (ii) 'n landboumiddel gebruik nie tensy hy 'n plaagbeheeroperateur is wat ingevolge hierdie Wet geregistreer is of behalwe in die teenwoordigheid en onder die toesig van 'n plaagbeheeroperateur wat aldus geregistreer is. **[*(b)* Die bepalings van paragraaf *(a)* is, in die geval van 'n veemiddel, nie van toepassing nie op 'n veearts geregistreer kragtens die Veeartswet, 1933 (Wet 16 van 1933).]".**
		Die vervanging van artikel 7*bis* van Wet 36 van 1947, soos ingevoeg by artikel 1 van Wet 48 van 1950 en vervang by artikel 6 van Wet 60 van 1970 en artikel 9 van Wet 24 van 1977. 7. Artikel 7*bis* van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Verbod op verkryging, vervreemding, verkoop of gebruik van sekere misstowwe, veevoedsel en landboumiddels** 7*bis* (1) Die Minister kan by kennisgewing in die *Staatskoerant*— *(a)* die verkryging, vervreemding, verkoop of gebruik van misstowwe, veevoedsel of landboumiddels **[of veemiddels]** verbied; of *(b)* sodanige verkryging, vervreemding, verkoop of gebruik verbied, behalwe ooreenkomstig die voorwaardes in die kennisgewing bepaal of behalwe uit hoofde van en ooreenkomstig die voorwaardes gestel in 'n permit wat deur die registrateur uitgereik is, en kan so 'n kennisgewing op dergelike wyse herroep of wysig. (2) 'n Verbod kragtens subartikel (1) uitgevaardig, kan van toepassing wees— *(a)* dwarsdeur die Republiek of in een of meer vermelde gebiede; *(b)* op enige persoon of op persone wat tot 'n vermelde klas of groep persone behoort of op persone wat nie tot so 'n klas of groep persone behoort nie; of *(c)* ten opsigte van alle of een of meer klasse of soorte misstowwe, veevoedsel of landboumiddels **[of veemiddels].** (3) 'n Voorwaarde in subartikel (1) bedoel, is aan geen beperkings van watter aard ook al onderworpe nie, en sodanige voorwaardes kan ten opsigte van verskillende gebiede, persone of klasse of groepe persone verskil.

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		The substitution of section 9 of Act 36 of 1947 as amended by section 7 of Act 60 of 1970 and section 10 of Act 24 of 1977. 8. The following section is hereby substituted for section 9 of Act 36 of 1947: "**Invoices required in case of sale of fertilizers, farm feeds, agricultural remedies not in a container** **9.** Any person who sells any fertilizer, farm feed, or agricultural remedy **[or stock remedy]** not in a container, shall give to the purchaser at the time of delivery or send to him at the time of despatch an invoice setting forth such particulars in respect of such fertilizer, farm feed, or agricultural remedy **[or stock remedy]** as may be prescribed.
		The substitution of section 13 of Act 36 of 1947 as substituted by section 8 of Act 60 of 1970. 9. The following section is hereby substituted for section 13 of Act 36 of 1947: "**Exclusion of any fertilizer, farm feed, or agricultural remedy from operation of Act** **13.** The Minister may by notice in the *Gazette* exclude, subject to such conditions as he or she may determine, any fertilizer, farm feed, or agricultural remedy **[or stock remedy]** from the operation 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 13 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 analysts** **14.** For the purpose of this Act, the Minister may from time to time designate persons, including officers, as— *(a)* technical advisers who shall advise the registrar in regard to matters referred to them by the registrar; and *(b)* analysts to analyse samples of fertilizers, farm feeds, or agricultural remedies **[or stock remedies]** referred to them by the registrar, and to report thereon in the form and manner prescribed."

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		Die vervanging van artikel 9 van Wet 36 van 1947, soos gewysig by artikel 7 van Wet 60 van 1970 en artikel 10 van Wet 24 van 1977. 8. Artikel 9 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Fakture nodig in geval van verkoop van misstowwe, veevoedsel en landboumiddels nie in 'n houer nie** 9. Iemand wat 'n misstof, veevoedsel of landboumiddel **[of veemiddel]** nie in 'n houer verkoop nie, moet 'n faktuur met sodanige besonderhede ten opsigte van so 'n misstof, veevoedsel of landboumiddel **[of veemiddel]** as wat voorgeskryf mag wees, ten tyde van aflewering aan die koper oorhandig of ten tyde van versending aan hom stuur.".
		Die vervanging van artikel 13 van Wet 36 van 1947, soos vervang by artikel 8 van Wet 60 van 1970. 9. Artikel 13 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Uitsluiting van misstof, veevoedsel of landboumiddel van toepassing van Wet** 13. Onderworpe aan sodanige voorwaardes as wat hy of sy mag bepaal, kan die Minister by kennisgewing in die *Staatskoerant* 'n misstof, veevoedsel of landboumiddel **[of veemiddel]** uitsluit van die toepassing van enigeen, of van al die bepalings van hierdie Wet.".
		Die vervanging van artikel 14 van Wet 36 van 1947, soos gewysig by artikel 35 van Wet 28 van 1961 en vervang by artikel 9 van Wet 60 van 1970 en artikel 13 van Wet 24 van 1977. 10. Artikel 14 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Aanwysing van tegniese adviseurs en ontleders** 14. Die Minister kan van tyd tot tyd vir die doeleindes van hierdie Wet persone, met inbegrip van beamptes, aanwys as — *(a)* tegniese adviseurs wat die registrateur van advies moet dien aangaande aangeleenthede wat deur die registrateur na hulle verwys word; en *(b)* ontleders om monsters van misstowwe, veevoedsel of landboumiddels **[of veemiddels]** wat deur die registrateur na hulle verwys word, te ontleed en op die voorgeskrewe vorm en wyse daaroor verslag te doen.".

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		The substitution of section 15 of Act 36 of 1947 as amended by section 36 of Act 28 of 1961, section 10 of Act 60 of 1970 and substituted by section 14 of Act 24 of 1977 11. 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 or 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 of 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, farm 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, farm feed, or agricultural remedy or any quantity thereof, which has so been seized, and

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		Die vervanging van artikel 15 van Wet 36 van 1947, soos gewysig by artikel 36 van Wet 28 van 1961 en artikel 10 van Wet 60 van 1970 en vervang by artikel 14 van Wet 24 van 1977. 10. Artikel 15 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Bevoegdheid tot betreding van persele, ondersoeke, ontleding van monsters, en beslaglegging** 15. (1) Die registrateur, handelende op gesag van en in ooreenstemming met 'n lasbrief uitgereik kragtens artikel 15A, kan te alle redelike tye— (a) 'n plek, perseel of voertuig betree en ondersoek ten opsigte waarvan hy of sy rede op redelike gronde vermoed dat daarop of daarin 'n misstof, veevoedsel of landboumiddel vervaardig, verwerk, behandel, berei, gegradeer, geklassifiseer, verpak, gemerk, geëtiketteer, gehou, gebottel, verwyder, vervoer, uitgestal, verkoop of gebruik word, en enige sodanige misstof, veevoedsel of landboumiddel of enige bestanddeel daarvan ondersoek of toets; *(b)* enige boek of stuk op of in enige plek, perseel of voertuig bedoel in paragraaf *(a)* ondersoek ten opsigte waarvan hy of sy redelike gronde het om te glo dat hulle op 'n sodanige misstof, veevoedsel of landboumiddel of enige bestanddeel daarvan betrekking het, en afskrifte van of uittreksels uit sodanige boek of stuk maak; *(c)* enige werksaamhede of prosesse ondersoek wat in verband met die vervaardiging, verwerking, behandeling, bereiding, gradering, klassifisering, verpakking, merk, etikettering, hou, bottelering, verwydering, vervoer, uitstalling, verkoop of gebruik van 'n misstof, veevoedsel of landboumiddel, verrig word op 'n plek of perseel bedoel in paragraaf *(a)* en van die persoon wat oor sodanige werksaamhede of prosesse toesig hou, of van die eienaar van 'n misstof, veevoedsel of landboumiddel of bestanddeel daarvan, of van die persoon wat dit in sy of haar bewaring het, enige tersaaklike inligting of verduideliking eis aangaande daardie werksaamhede of prosesse, of misstof, veevoedsel of landboumiddel of bestanddeel; *(d)* van die eienaar van 'n boek of stuk bedoel in paragraaf *(b)*, of die persoon wat dit in sy of haar bewaring het, 'n verduideliking eis aangaande 'n aantekening of inskrywing daarin; *(e)* beslag lê op enige boek, stuk, misstof, veevoedsel of landboumiddel wat bewys kan lewer van 'n misdryf ingevolge hierdie Wet, of op enige hoeveelheid van 'n misstof, veevoedsel of landboumiddel ten opsigte waarvan daar rede is om te glo dat so 'n misdryf gepleeg is, en enige boek, stuk, misstof, veevoedsel of landboumiddel, of enige hoeveelheid daarvan, waarop aldus beslag gelê is, van die betrokke plek, perseel of voertuig verwyder of daarop of daarin

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		may in his discretion place on such book, document, fertilizer, farm feed, or agricultural or the container thereof, such identification mark or seal as he may deem necessary; *(f)* take samples or 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 or 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 the 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, or, if such owner or person is not available, in the presence of any other witness; and *(c)* in the 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(1) 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—

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		laat, en na goeddunke op sodanige boek, stuk, misstof, veevoedsel of landboumiddel of 'n houer daarvan, die identifikasiemerk of -seël aanbring wat hy nodig ag; *(f)* monsters neem of laat neem van 'n misstof, veevoedsel of landboumiddel of 'n bestanddeel daarvan, en 'n houer oopmaak wat wel of na vermoede enigiets bevat wat gebruik word of bestem is vir gebruik by die vervaardiging, verwerking, behandeling, bereiding, gradering, klassifisering, verpakking, merk, etikettering, hou, bottelering, verwydering, vervoer, uitstalling of verkoop van enige misstof, veevoedsel of landboumiddel, en daardie monsters ondersoek, ontleed, gradeer of klassifiseer, of laat ondersoek, ontleed, gradeer of klassifiseer. (2) Waar die registrateur 'n ondersoek ingevolge subartikel (1) uitvoer in die teenwoordigheid van iemand wat daardeur geraak word, toon hy of sy eers sy of haar skriftelike magtiging aan so 'n persoon. (3) 'n Monster wat ingevolge subartikel (1) geneem is, moet— *(a)* volgens die voorgeskrewe metode geneem word; *(b)* in die teenwoordigheid van die eienaar van die misstof, veevoedsel of landboumiddel of bestanddeel daarvan, of van die persoon wat dit in sy bewaring het, geneem word, of, indien sodanige eienaar of persoon nie beskikbaar is nie, in die teenwoordigheid van enige ander getuie; en *(c)* in die teenwoordigheid van sodanige eienaar of persoon, of sodanige getuie, in drie dele verdeel en elke deel moet in 'n geskikte houer verpak en met 'n seël verseël word en op so 'n wyse as wat die aard daarvan toelaat, geëtiketteer of gemerk word sodat daardie monster geredelik geïdentifiseer kan word. (4) Een deel elk van die monster wat aldus verdeel is, moet— *(a)* aan sodanige eienaar of persoon oorhandig of per geregistreerde pos gestuur word; *(b)* tesame met 'n sertifikaat in die voorgeskrewe vorm aan 'n ontleder gestuur word wat die genoemde deel so spoedig doenlik moet toets, ondersoek of ontleed ooreenkomstig die metodes wat deur die registrateur bepaal word, en die uitslag van so 'n toets, ondersoek of ontleding moet deur daardie ontleder op die voorgeskrewe vorm aangeteken en aan die registrateur voorgelê word; en *(c)* deur die registrateur bewaar word. (5) Die eienaar van iets waaruit 'n monster bedoel in subartikel (1)*(f)* geneem is, kan 'n bedrag gelykstaande met die markwaarde van daardie monster van die registrateur eis. (6) Behoudens artikel 15A(1) kan die registrateur gedurende die dag sonder 'n lasbrief enige plek, perseel of voertuig betree en ondersoek nadat hy of sy hom of haar geïdentifiseer het en ooreenkomstig artikel 15 die bevoegdhede van beslaglegging, verwydering, aanhouding, insameling van bewyse en deursoeking (uitgesonderd die bevoegdheid om 'n persoon te deursoek) uitoefen, indien—

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		(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 that— (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 not serve as authority for, and may not be applied for the purpose of, entering and searching any private dwelling, nor for conducting such seizure and removal, the collection of 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.** (1) 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 the registrar seeking the warrant may be asked to specify which of the 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.

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		(a) die persoon wat bevoeg is om toestemming te gee vir die betreding en vir sodanige deursoeking, beslaglegging, verwydering en aanhouding, daardie toestemming gee; of (b) die registrateur op redelike gronde van mening is dat— (i) die vereiste lasbrief aan hom of haar uitgereik sal word ingevolge artikel 15A indien hy of sy daarom sou aansoek doen; en (ii) die vertraging wat veroorsaak sou word deur eers die lasbrief te kry, die doel of oogmerk van die betreding, deursoeking, beslaglegging, verwydering, aanhouding, insameling van bewyse en ander stappe sal verydel. (7) Subartikel (6)*(b)* geld nie as magtiging vir, en mag nie toegepas word vir die doel van, die betreding en deursoeking van enige private woning nie en ook nie vir die doen van sodanige beslaglegging en verwydering, die insameling van bewyse en die doen van gemelde ander stappe daarin nie.".
		Die invoeging van artikel 15 in Wet 36 van 1947. **11.** Die volgende artikel word hierby na artikel 15 van Wet 36 van 1947 ingevoeg: **"Bepalings rakende uitreiking en uitvoering van lasbrief** 15A. (1) Die lasbrief in artikel 15 beoog, moet in kamers uitgereik word deur 'n regter van die Hoë Hof of deur 'n landdros wat jurisdiksie het in die gebied waar enige misstof, veevoedsel of landboumiddel vervaardig, verwerk, behandel, berei, gegradeer, geklassifiseer, verpak, gemerk, geëtiketteer, gehou, gebottel, verwyder, vervoer, uitgestal, verkoop of gebruik is of word of waarskynlik sal word, en moet uitgereik word slegs indien dit vir sodanige regter of landdros uit inligting onder eed of bevestiging blyk dat daar redelike gronde is om te vermoed dat enige misstof, veevoedsel of landboumiddel vervaardig, verwerk, behandel, berei, gegradeer, geklassifiseer, verpak, gemerk, geëtiketteer, gehou, gebottel, verwyder, vervoer, uitgestal, verkoop of gebruik is of word of waarskynlik sal word, en die registrateur wat die lasbrief wil hê, kan gevra word om te spesifiseer watter van die bevoegdhede in artikel 15A beoog, waarskynlik uitgeoefen sal word. (2) 'n Lasbrief ingevolge hierdie artikel kan op enige dag uitgereik word en bly van krag totdat— *(a)* dit uitgevoer is; of *(b)* dit ingetrek word deur die regter of landdros wat dit uitgereik het of, indien nie beskikbaar nie, deur 'n ander regter of deur 'n ander landdros met soortgelyke gesag; of *(c)* een maand verloop het sedert die dag van uitreiking daarvan; of *(d)* die doel waarvoor die lasbrief uitgereik is, nie meer bestaan nie, wat ook al eerste gebeur.

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		(3) A warant 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-

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		(3) 'n Lasbrief uitgereik kragtens hierdie artikel, mag net in die dag uitgevoer word, tensy die persoon wat die lasbrief uitgereik het, die uitvoering daarvan in die nag gemagtig het, op tye wat redelik is, en die betreding en deursoeking van enige plek, perseel of voertuig in die lasbrief vermeld, en die deursoeking van enige persoon daarin of daarop moet geskied met streng inagneming van ordentlikheid en orde, insluitende— *(a)* 'n persoon se reg op, respek vir en beskerming van sy of haar waardigheid; *(b)* die reg van 'n persoon op vryheid en sekuriteit van sy of haar persoon; en *(c)* die reg van 'n persoon op sy of haar persoonlike privaatheid. (4) Die registrateur wat 'n lasbrief ingevolge hierdie artikel uitvoer, moet onmiddellik voor die begin van die uitvoering daarvan— *(a)* hom of haar identifiseer teenoor die persoon in beheer van die plek, perseel of voertuig wat betree is of gaan word, indien daardie persoon teenwoordig is, en aan daardie persoon 'n afskrif van die lasbrief oorhandig, maar as daar nie so 'n persoon teenwoordig is nie, moet hy of sy 'n afskrif van die lasbrief op 'n opvallende plek op die plek, perseel of voertuig aanbring; *(b)* daardie persoon op sy of haar versoek voorsien van besonderhede rakende die registrateur se gesag om sodanige lasbrief uit te voer; *(c)* vir doeleindes van paragraaf *(b)* kan die registrateur versoek word om die sertifikaat wat ingevolge artikel 26 ten opsigte van hom of haar uitgereik is, te toon. (5) Die registrateur kan sodanige geweld gebruik as wat redelikerwys nodig is om enige weerstand teen betreding en deursoeking te oorkom. (6) Die registrateur kan enige plek, perseel of voertuig betree en deursoek, en kan enige persoon daarop of daarin deursoek, slegs indien hy of sy eers hoorbaar toegang daartoe geëis het en die doel van die betreding bekend gemaak het, tensy die registrateur op redelike gronde van mening is dat daar met enige misstof, veevoedsel of landboumiddel, boek of stuk wat die onderwerp van 'n deursoeking is, gepeuter kan word of dat dit vernietig kan word of verlore kan gaan indien toegang eers geëis en daardie doel bekend gemaak word. (7) Indien tydens die uitvoering van 'n lasbrief ingevolge hierdie artikel 'n persoon daarop aanspraak maak dat enige goedere, stuk, boek of artikel wat by, op of in die onderhawige plek, perseel of voertuig gevind is, geprivilegieerde inligting bevat en weier om dit te laat inspekteer of verwyder, kan die registrateur wat die lasbrief uitvoer, indien hy of sy van mening is dat die goedere, stuk, boek of artikel tersaaklik en nodig is vir die ondersoek of enige klag of enige beweerde of verdagte vervaardiging, verwerking, behandeling, bereiding, gradering, klassifisering,

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		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 relevant 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, books or articles for safe custody until the court has made a ruling on the question whether or not the information in question is privileged. (8) In undertaking any search for and inspection and seizure of suspected goods, documents, books 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 be conducted, and subsections (4), (5), (6), (7) and (8) shall apply *mutatis mutandis* to the registrar acting by virtue of section 15(6).".
		The substitution of section 16 of 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 16 of 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 agricul tural remedy **[or 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 sub stance derived from the carcass of an animal, a permit referred to in section 12 has been issued in respect thereof.

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		verpakking, merk, etikettering, hou, verwydering, vervoer, uitstalling, verkoop of gebruik tersaaklik en nodig is vir die ondersoek na enige klag of beweerde of verdagte vervaardiging, verwerking, behandeling, bereiding, gradering, klassifisering, verpakking, merk, etikettering, hou, verwydering, vervoer, uitstalling, verkoop of gebruik, moet die griffier van die Hoë Hof wat jurisdiksie het, of die griffier se adjunk, versoek om op sodanige goedere, stukke, boeke of artikels beslag te lê en dit te verwyder vir veilige bewaring totdat die hof uitspraak gelewer het oor die vraag of die onderhawige inligting geprivilegieerd is al dan nie. (8) Wanneer die registrateur enige deursoeking vir en inspeksie van en beslaglegging op verdagte goedere, stukke, boeke of artikels doen, kan die registrateur bygestaan word deur die klaer (as daar is) of enige kundige persoon om enige misstof, veevoedsel of landboumiddel te identifiseer. (9) Geen antwoord of verklaring gegee deur enige persoon aan die registrateur wat sy of haar bevoegdhede uitoefen ingevolge artikel 15(1)*(c)* en *(d)* of gegee of verleen aan die registrateur wat soortgelyke bevoegdhede kragtens artikel 15(6) uitoefen, indien dit selfinkriminerend is, is toelaatbaar as getuienis teen daardie persoon in strafregtelike verrigtinge wat in enige hof teen hom of haar ingestel word nie. (10) Die bepalings van subartikel (2) rakende die wyse waarop 'n deursoeking gedoen moet word, en subartikels (4), (5), (6), (7) en (8) is *mutatis mutandis* van toepassing op die registrateur wat kragtens artikel 15(6) optree.".
		Die vervanging van artikel 16 van Wet 36 van 1947, soos gewysig by artikel 37 van Wet 28 van 1961 en artikel 2 van Wet 17 van 1972 en vervang by artikel 15 van Wet 24 van 1977. 12. Artikel 16 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"12 Invoer van misstowwe, veevoedsel en landboumiddels** 16. (1) Niemand mag 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] in die Republiek invoer nie tensy— *(a)* daardie misstof, veevoedsel of landboumiddel 1[of veemiddel] kragtens hierdie Wet geregistreer is, so saamgestel en so doeltreffend is as wat in die aansoek om registrasie daarvan gespesifiseer is, alle chemiese, fisiese en ander eienskappe aldus gespesifiseer, besit, voldoen aan die vereistes wat ten opsigte daarvan voorgeskryf is en verpak is in 'n verseëlde houer wat op die voorgeskrewe wyse met die voorgeskrewe besonderhede gemerk of geëtiketteer is; *(b)* in die geval van 'n misstof of veevoedsel wat been of 'n ander stof afkomstig van die karkas van 'n dier bevat, 'n permit bedoel in artikel 12 daarvoor uitgereik is.

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		(2) Notwithstanding the provisions of subsection (1) the registrar may, in his or her discretion and on such conditions as he or she may determine, in writing permit the import of any consignment of any fertilizer, farm feed, or agricultural remedy **[or stock remedy]** which does not comply with the requirements referred to in subsection (1)*(a)*. (3) Fertilizers, farm feeds, or agricultural remedies **[or stock remedies]** imported shall— *(a)* only be imported through a prescribed port or place; *(b)* if a sample thereof has thus been taken, not be sold in the Republic except on the written authority of the registrar and subject to the conditions specified therein. (4) The provisions of section 15 relating to samples shall *mutatis mutandis* apply with reference to a sample taken in terms of this section. (5) If any fertilizer, farm feed, or agricultural remedy **[or stock remedy]**, which in terms of subsection (3) *(b)* may not be removed from a port or place, is found to comply with the requirements of this Act, no rent charges shall be payable 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 to forward that fertilizer, farm feed, or agricultural remedy **[or stock remedy]**, in respect of any portion of the period in question which is subsequent to the presentation to the Railways Administration of a delivery order, or a forwarding order, as the case may be. (6) *(a)* If any fertilizer, farm feed, or agricultural remedy **[or stock remedy]** has been imported contrary to the provisions of this section, such fertilizer, farm feed, or agricultural remedy **[or stock remedy]** shall at the option of the importer thereof— (i) at the expense of such importer be removed by him or her from the Republic within such period as the registrar may determine; or (ii) be forfeited to the State and be either destroyed or otherwise disposed of as the registrar may direct, and if such importer fails to remove such fertilizer, farm feed, or agricultural remedy **[or stock remedy]** in terms of the provisions of subparagraph *(i)* within the period referred to in that subparagraph, it shall be forfeited to the State, and be either destroyed or otherwise disposed of as the registrar may direct.

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		(2) Ondanks die bepalings van subartikel (1) kan die registrateur na goeddunke en op die voorwaardes wat hy of sy bepaal, skriftelik die invoer van enige besending misstof, veevoedsel of landboumiddel 1[of veemiddel] toelaat wat nie voldoen aan die vereistes bedoel in subartikel (1) *(a)* nie. (3) Misstowwe, veevoedsel of landboumiddels 1[of veemiddels] wat ingevoer word— *(a)* mag slegs deur 'n voorgeskrewe hawe of plek ingevoer word; *(b)* mag, indien die registrateur gelas dat 'n monster daarvan geneem moet word, nie sonder die skriftelike magtiging van die registrateur van so 'n hawe of plek verwyder word nie; *(c)* moet, indien die registrateur aldus gelas, op die voorgeskrewe wyse vir ondersoek en die neem van 'n monster by so 'n hawe of plek beskikbaar gestel word; en *(d)* mag, indien 'n monster daarvan aldus geneem is, nie in die Republiek verkoop word nie behalwe ingevolge 'n skriftelike magtiging van die registrateur en onderworpe aan die voorwaardes daarin uiteengesit. (4) Die bepalings van artikel 15 betreffende monsters is *mutatis mutandis* van toepassing op 'n monster wat kragtens hierdie artikel geneem word. (5) Indien bevind word dat 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] wat ingevolge subartikel (3)*(b)* nie van 'n hawe of plek verwyder mag word nie aan die vereistes van hierdie Wet voldoen, dan is daar geen geld deur die invoerder betaalbaar ten opsigte van die tydperk waarin dit nie so verwyder mag word nie, of, indien van die Spoorwegadministrasie verlang word om daardie misstof, veevoedsel of landboumiddel 1[of veemiddel] af te lewer of aan te stuur, ten opsigte van enige gedeelte van die bedoelde tydperk wat volg op die indiening by die Spoorwegadministrasie van 'n afleweringsopdrag, of, na gelang van die geval, van 'n versendingsopdrag. (6) *(a)* Wanneer 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] strydig met die bepalings van hierdie artikel ingevoer is, word die misstof, veevoedsel of landboumiddel 1[of veemiddel] na die keuse van die invoerder daarvan— (i) op die koste van die bedoelde invoerder deur hom of haar uit die Republiek verwyder binne die tydperk deur die registrateur bepaal; of (ii) aan die Staat verbeur en word dit óf vernietig óf op 'n ander wyse mee gehandel, na gelang die registrateur gelas, en indien bedoelde invoerder versuim om sodanige misstof, veevoedsel of landboumiddel 1[of veemiddel] binne die tydperk bedoel in subparagraaf *(i)* ingevolge die bepalings van daardie subparagraaf te verwyder, word dit aan die Staat verbeur en óf vernietig óf op 'n ander wyse mee gehandel na gelang die registrateur gelas.

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		(b) Any costs incurred by the State in connection with the destruction or disposal of any fertilizer, farm feed, or agricultural remedy **[or stock remedy]** in terms of the provisions of paragraph *(a)*, may be recovered from the importer concerned." The substitution of section 18 of Act 36 of 1947 as amended by section 2 of Act 48 of 1950, section 38 of Act 28 of 1961, section 11 of Act 60 of 1970, section 16 of Act 24 of 1977 and section 8*(b)* of Act 4 of 1980 13. The following section is hereby substituted for section 18 of Act 36 of 1947: **"Offences and penalties** **18.** (1) Any person who— *(a)* fails to comply with the provisions of section 9; *(b)* obstructs or hinders the registrar, any technical adviser or any analyst in the exercise of his or her powers or performance of his or her duties under this Act; *(bA)* fails to make any statement or give any explanation if he is requested thereto by the registrar in the exercise of his powers or the performance of his duties under this Act; *(bB)* fails to comply with an order issued under section 6A; *(c)* contravenes 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 fertilizers, farm feeds, or agricultural remedies **[or stock remedies]** contrary to a prohibition issued under section 7*bis*; *(e)* tampers with any sample taken in terms of this Act, or with anything seized in terms of this Act; *(f)* makes use, in connection with any fertilizer, farm feed, or agricultural remedy **[or stock remedy]**, of any certificate, invoice or other document issued in respect of any other fertilizer, farm feed, or agricultural remedy **[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 remedy **[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 referred to in section 7*bis* (1)*(b)*; (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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		(b) Enige koste deur die Staat aangegaan in verband met die vernietiging van of handeling met 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] ingevolge die bepalings van paragraaf *(a)*, kan op die betrokke invoerder verhaal word.".
		Die vervanging van artikel 18 van Wet 36 van 1947, soos gewysig by artikel 2 van Wet 48 van 1950, artikel 38 van Wet 28 van 1961, artikel 11 van Wet 60 van 1970, artikel 16 van Wet 24 van 1977 en artikel 8 *(b)*van Wet 4 van 1980. 13. Artikel 18 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: "**Oortredings en strafbepalings** 18. (1) Iemand wat— *(a)* versuim om aan die bepalings van artikel 9 te voldoen; *(b)* die registrateur, 'n tegniese raadgewer of 'n ontleder by die uitoefening van sy of haar bevoegdhede of die uitvoering van sy of haar pligte ingevolge hierdie Wet hinder of dwarsboom; (bA) in gebreke bly om 'n verklaring te maak of 'n verduideliking te verstrek wanneer hy of sy deur die registrateur by die uitoefening van sy of haar bevoegdhede of uitvoering van sy of haar pligte kragtens hierdie Wet daarom versoek word; (bB) versuim om te voldoen aan 'n lasgewing uitgereik kragtens artikel 6A; *(c)* die bepalings van artikel 7, 8, 10, 12 of 16 of met 'n voorwaarde beoog in artikel 3 (3), 16 (2) of 16 (3) *(d)* oortree of versuim om daaraan te voldoen; *(c)bis* in stryd met 'n kragtens artikel 7*bis* uitgevaardigde verbod misstowwe, veevoedsel of landboumiddels 1[of veemiddels] verkry, vervreem, verkoop of gebruik; *(e)* aan 'n monster wat ooreenkomstig hierdie Wet geneem is, of aan enigiets waarop ooreenkomstig hierdie Wet beslag gelê is, peuter; *(f)* in verband met 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] gebruik maak van 'n sertifikaat, faktuur of ander dokument wat in verband met 'n ander misstof, veevoedsel of landboumiddel 1[of veemiddel] uitgereik is of wat nie meer geldig is nie; *(g)* in verband met enige misstof, veevoedsel of landboumiddel 1[of veemiddel] 'n valse of misleidende verklaring maak— (i) in 'n aansoek om registrasie daarvan; (ii) in 'n faktuur ingevolge artikel 9 uitgereik; (iii) in 'n advertensie daarvan; (iv) by die verkoop daarvan; (v) in 'n aansoek om 'n in artikel 7*bis* (1) *(b)* bedoelde permit; (vi) in 'n kennisgewing bedoel in artikel 10; (vii) wanneer hy ooreenkomstig die bepalings van artikel 16 (1) *(b)* optree;

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		(h) sells any fertilizer, farm feed, or agricultural remedy **[or stock remedy]** upon the container of which a false or misleading statement in connection with such contents is printed or written; *(i)* sells any fertilizer, farm feed, or agricultural remedy **[or stock remedy]** which is not of the kind, nature, composition, strength, potency or quality described or represented when so sold; *(j)* having been duly summoned in terms of section 6 (4) *(a)* to appear before the board, fails without lawful excuse so to appear; *(k)* having appeared as a witness before the board, refuses without lawful excuse to be sworn or to make affirmation or to produce any document or answer any question which he or she may be lawfully required to produce or answer; *(l)* fails to comply with the provisions of section 4A (1) or (3), shall be guilty of an offence and liable on conviction— (i) in the case of a contravention under paragraph *(a)*, *(b)*, *(bA)* or *(l)* to a fine not exceeding five hundred rand or imprisonment for a period not exceeding twelve months or to both such fine and such imprisonment; and (ii) in the case of a contravention under paragraph (bB), *(c)*, *(c)bis*, *(e)*, *(f)*, *(g)*, *(h)*, *(i)*, *(j)* or *(k)* to a fine not exceeding one thousand rand or imprisonment for a period not exceeding two years or to both such fine and such imprisonment. (2) The court convicting any person of an offence under this Act, may, upon the application of the prosecutor, declare any fertilizer, farm feed, or agricultural remedy **[or stock remedy]** in respect of which the offence has been committed and all fertilizers, farm feeds, or agricultural remedies **[or stock remedies]** of a similar nature to that in respect of which such person has been convicted, and of which such person is the owner, or which are in his possession, to be forfeited to the State. (3) All fertilizers, farm feeds, or agricultural remedies **[or stock remedies]** forfeited under this Act shall be destroyed or otherwise dealt with as the Minister may direct."
		The substitution of section 20 of Act 36 of 1947 as amended by section 39*(a)* of Act 28 of 1961 and section 17 of Act 24 of 1977 14. The following section is hereby substituted for section 20 of Act 36 of 1947: "**Procedure and evidence** **20.** (1) In any criminal proceedings under this Act—

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		(h) 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] op die houer waarvan 'n valse of misleidende bewering in verband met die inhoud daarvan gedruk of geskryf is, verkoop; (i) 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] verkoop wat nie van die soort, aard, samestelling, sterkte, vermoë of gehalte is nie wat beskryf of voorgegee word wanneer dit aldus verkoop word; (j) nadat hy of sy behoorlik kragtens artikel 6 (4) *(a)* gedagvaar is om voor die raad te verskyn, sonder wettige rede versuim om aldus te verskyn; (k) nadat hy of sy as 'n getuie voor die raad verskyn het, sonder wettige rede weier om beëdig te word of 'n bevestiging te doen, of om 'n stuk oor te lê of 'n vraag te beantwoord wat hy of sy wettiglik aangesê kan word om oor te lê of te beantwoord; (l) in gebreke bly om te voldoen aan die bepalings van artikel 4A (1) of (3), is aan 'n misdryf skuldig en by skuldigbevinding strafbaar— (i) in die geval van 'n oortreding ingevolge paragraaf *(a)*, *(b)*, (bA) of *(l)*, met 'n boete van hoogstens vyfhonderd rand of gevangenisstraf vir 'n tydperk van hoogstens twaalf maande of met sowel daardie boete as daardie gevangenisstraf; en (ii) in die geval van 'n oortreding ingevolge paragraaf (bB), *(c)*, *(c)*bis *(e)*, *(f)*, *(g)*, *(h)*, *(i)*, *(j)* of *(k)*, met 'n boete van hoogstens een duisend rand of gevangenisstraf vir 'n tydperk van hoogstens twee jaar of met sowel daardie boete as daardie gevangenisstraf. (2) Die hof wat iemand weens 'n oortreding ingevolge hierdie Wet veroordeel, kan op aansoek van die aanklaer enige misstof, veevoedsel of landboumiddel 1[of veemiddel] in verband waarmee die oortreding begaan is, en alle misstowwe, veevoedsel of landboumiddels 1[of veemiddels] van 'n aard soortgelyk aan dié ten opsigte waarvan so 'n persoon veroordeel is en waarvan daardie persoon die eienaar is, of wat hy of sy in sy of haar besit het, aan die Staat verbeurd verklaar. (3) Alle kragtens hierdie Wet verbeurdverklaarde misstowwe, veevoedsel of landboumiddels 1[of veemiddels] word vernietig of andersins mee gehandel soos die Minister gelas.".
		Die vervanging van artikel 20 van Wet 36 van 1947, soos gewysig by artikel 39 *(a)* van Wet 28 van 1961 en artikel 17 van Wet 24 van 1977. 14. Artikel 20 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: "**Prosedure en bewyslewering** 20. (1) In 'n strafgeding ingevolge hierdie Wet—

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		(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 stock 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;

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		(a) word, tensy die teendeel bewys word, veronderstel dat 'n hoeveelheid van 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] wat in of op 'n perseel, plek, vaartuig of voertuig is wanneer 'n monster daarvan ooreenkomstig die bepalings van hierdie Wet geneem word, van dieselfde samestelling is, dieselfde mate van doeltreffendheid het, en in alle ander opsigte dieselfde eienskappe besit as daardie monster; *(b)* word dit geag dat wanneer daar bewys gelewer is dat iemand aan 'n monster geknoei het, so iemand met frauduleuse bedoeling gehandel het, tensy die teendeel bewys word; *(c)* word 'n sertifikaat waarin die resultaat van 'n ontleding of toets wat ingevolge die bepalings van subartikel (3) van artikel *vyftien* uitgevoer is, aangeteken is, en wat heet deur die ontleder wat die ontleding of toets uitgevoer het onderteken te wees, aangeneem as *prima facie*-bewys van die daarin vermelde feite; *(d)* is 'n verklaring of inskrywing wat bevat is in 'n boek of geskrif wat deur 'n fabrikant, invoerder of eienaar van 'n misstof, veevoedsel of landboumiddel 1[of veemiddel], of deur die bestuurder, agent of werknemer van so iemand gehou word, of wat gevind word op of in 'n perseel in okkupasie van so iemand, of op 'n voertuig wat in die besigheid van so iemand gebruik word, toelaatbaar by wyse van getuienis teen hom of haar as 'n erkenning van die feite uiteengesit in daardie verklaring of inskrywing, tensy dit bewys word dat daardie verklaring of inskrywing nie deur so iemand of deur 'n bestuurder, agent of werknemer van so iemand in die loop van sy of haar werk as bestuurder of in die loop van sy of haar agentskap of diens gemaak is nie. (2) Geen vervolging mag ingestel word as gevolg van 'n ontleding of toets gemaak ingevolge die bepalings van artikel *vyftien* of artikel *sestien* nie, tensy 'n afskrif van die ontleder se sertifikaat ten minste een-en-twintig dae voor die instelling van sodanige vervolging aan die persoon wat die beskuldigde gaan wees, aangestuur is.".
		Die vervanging van artikel 21 van Wet 36 van 1947, soos gewysig by artikel 40 van Wet 28 van 1960 en artikel 12 van Wet 60 van 1970 en vervang by artikel 18 van Wet 24 van 1977. 15. Artikel 21 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: **"Spesiale verdediging in geval van vervolgings** 21. Indien iemand beskuldig word van die verkoop van 'n misstof, veevoedsel of landboumiddel 1[of veemiddel], in stryd met die bepalings van artikel 7 (1) *(d)*, is dit 'n voldoende verdediging as hy of sy tot bevrediging van die hof bewys— *(a)* dat hy of sy daardie misstof, veevoedsel of landboumiddel 1[of veemiddel] onder 'n geregistreerde naam of merk gekoop het, asof dit in alle opsigte dieselfde was as die artikel wat hy of sy voorgegee het om te verkoop;

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		(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 omit to do, then unless it is proved that— *(a)* in doing or omitting to do that act the manager, agent or employee was acting without the connivance or the permission of the 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 the manufacturer, importer or owner. (3) Any such manager, agent or employee may be 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 60 of 1970, section 20 of Act 24 of 1977 and section 9*(a)* of Act 4 of 1980

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		(b) dat hy of sy ten tyde van die verkoping geen rede gehad het om te vermoed dat dit in enige opsig van daardie artikel verskil nie; *(c)* dat hy of sy dit in die oorspronklike houer en in die toestand waarin dit was toe hy of sy dit aangekoop het, verkoop het; en *(d)* dat die houer daarvan aan die voorgeskrewe vereistes voldoen het en op die voorgeskrewe wyse verseël en met die voorgeskrewe besonderhede geëtiketteer of gemerk was.".
		Die vervanging van artikel 22 van Wet 36 van 1947, soos gewysig by artikel 41 van Wet 28 van 1961 en artikel 19 van Wet 24 van 1977. 16. Artikel 22 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: "1Dade of versuim van bestuurders, agente of werknemers 22. (1) Wanneer 'n bestuurder, agent of werknemer van 'n fabrikant, invoerder of eienaar van 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] enige daad of versuim begaan wat 'n misdryf ingevolge hierdie Wet sou wees as daardie fabrikant, invoerder of eienaar dit begaan het, dan, tensy dit bewys word dat— *(a)* die fabrikant, invoerder of eienaar daardie daad of versuim van die bestuurder, agent of werknemer nie deur die vingers gesien of toegelaat het nie; en *(b)* die fabrikant, invoerder of eienaar alle redelike stappe gedoen het om so 'n daad of versuim te voorkom; en *(c)* 'n daad of versuim, hetsy wettig of onwettig, van die ten laste gelegde aard onder geen voorwaardes of omstandighede binne die bestek van die bevoegdheid of in die diensloop van die bestuurder, agent of werknemer geval het nie, word veronderstel dat die fabrikant, invoerder of eienaar, na gelang van die geval, self die daad of versuim begaan het, en kan hy of sy ten opsigte daarvan skuldig bevind en gevonnis word; en die feit dat hy of sy 'n daad of versuim van die betrokke soort verbied het, strek op sigself nog nie tot voldoende bewys dat hy of sy alle redelike maatreëls getref het om die daad of versuim te voorkom nie. (2) Wanneer 'n bestuurder, agent of werknemer van sodanige fabrikant, invoerder of eienaar 'n daad of versuim begaan het wat 'n misdryf ingevolge hierdie Wet sou wees as sodanige fabrikant, invoerder of eienaar dit begaan het, kan hy of sy ten opsigte daarvan skuldig bevind en gevonnis word asof hy of sy daardie fabrikant, invoerder of eienaar is. (3) Sodanige bestuurder, agent of werknemer kan benewens so 'n fabrikant, invoerder of eienaar aldus skuldig bevind en gevonnis word.".
		Die vervanging van artikel 23 van Wet 36 van 1947, soos gewysig by artikel 42 *(a)* van Wet 28 van 1961, artikel 13 van Wet 60 van 1970, artikel 20 van Wet 24 van 1977 en artikel 9 *(a)* van Wet 4 van 1980.

No. and year of Law	Short title	Extent of Amendment
		17. The following section is hereby substituted for 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, imported 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, chemical, 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 any undertaking at any establishment; *(hB)* prescribing the records to be kept and the returns to be rendered in respect of registered sterilizing plants;

No en jaar van wet	Kort titel	Mate waarin gewysig
		17. Artikel 23 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: "**Regulasies** 23. (1) Die Minister kan regulasies uitvaardig— *(a)* wat die wyse waarop misstowwe, veevoedsel, landboumiddels 1[of veemiddels], steriliseringsinstallasies en plaagbeheeroperateurs geregistreer kan word, die wyse waarop so 'n registrasie hernuwe kan word en die inligting en die geld wat 'n aansoek om registrasie en hernuwing van registrasie moet vergesel, voorskryf; *'(b)* wat die beskrywing en voorwaardes waaronder 'n stof onder 'n besondere naam of merk as 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] geregistreer, ingevoer of verkoop mag word, voorskryf; *(c)* wat die wyse waarop en die tydperk waarin 'n appèl ingevolge artikel 6 1*[ses1]* aangeteken en voortgesit moet word, voorskryf; *(d)* wat die besonderhede voorskryf wat vermeld moet word in 'n faktuur wat ingevolge artikel 9 1*[nege1]* verstrek moet word; *(e)* wat die samestelling, doeltreffendheid, chemiese, fisiese of ander eienskap wat ten opsigte van een of ander stof vereis word sodat dit as 'n misstof, veevoedsel of landboumiddel 1[of veemiddel], na gelang van die geval, ingevoer, verkoop of geregistreer kan word, voorskryf;1 *(f)* wat die mate voorskryf waarin 'n misstof, veevoedsel of landboumiddel 1[of veemiddel] 'n tekort aan een of ander van sy bestanddele mag hê, en die verhouding waarin 'n bederfweringsmiddel, ontsmettingsmiddel of ander bestanddeel daarin aanwesig mag wees; *(g)* wat vereistes betreffende die massa en volume en houers waarin misstowwe, veevoedsel of landboumiddels 1[of veemiddels] verpak moet word, die wyse waarop hulle in sodanige houers verpak moet word, die wyse waarop sodanige houers verseël en geëtiketteer of gemerk moet word, en die besonderhede wat op sodanige etikette en houers moet verskyn, voorskryf; *(h)* wat die prosesse waarvolgens misstowwe, veevoedsel of landboumiddels 1[of veemiddels], of stowwe wat in die vervaardiging van misstowwe, veevoedsel of landboumiddels 1[of veemiddels] gebruik word, gesteriliseer moet word, en die wyse waarop steriliseringsinstallasies geïnspekteer moet word, voorskryf; *(hA)* wat die vereistes waaraan 'n aanleg moet voldoen, die praktyke wat gevolg moet word in die bedryf van 'n onderneming by 'n aanleg, die fasiliteite wat by 'n aanleg beskikbaar moet wees, en die aantekeninge wat gehou en die inligting wat ten opsigte van 'n aanleg en die bedryf van 'n onderneming by 'n aanleg verstrek moet word, voorskryf; *(hB)* wat die aantekeninge wat ten opsigte van geregistreerde steriliseringsinstallasies gehou en die opgawes wat ten opsigte van sodanige steriliseringsinstallasies verstrek moet word, voorskryf;

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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 to render returns in the form and manner and at the times prescribed; *(m)* prohibiting the disposal, acquisition or use of 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 in respect of different classes or kinds of fertilizers, 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) Before any regulations are made under this section, such regulations shall be published by the Minister in the *Gazette* together with a notice intimating that it 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 be 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 en jaar van wet	Kort titel	Mate waarin gewysig
		(hC) wat die aantekeninge wat deur geregistreerde plaagbeheeroperateurs gehou en die opgawes wat deur sodanige plaagbeheeroperateurs verstrek moet word, voorskryf; *(i)* om vervalsing van misstowwe, veevoedsel of landboumiddels 1[of veemiddels] en knoeiing met die houers daarvan te voorkom; *(j)* wat die metodes wat gevolg moet word, die gelde wat betaal moet word, en die sertifikate wat uitgereik moet word ten opsigte van die ondersoek, ontleding of toetsing van monsters ingevolge hierdie Wet geneem, voorskryf; *(k)* om die gebruik van valse of misleidende bewerings in advertensies van misstowwe, veevoedsel of landboumiddels 1[of veemiddels] te voorkom1; *(l)* wat bepaal dat iemand wat misstowwe, veevoedsel of landboumiddels 1[of veemiddels] in sy of haar besit of onder sy of haar beheer het, aantekenings met1 betrekking daartoe in die voorgeskrewe vorm en op die voorgeskrewe wyse moet hou, en opgawes in die vorm, op die wyse en op die tye wat voorgeskryf mag wees, moet verstrek; *(m)* wat die van die hand sit, verkryging of verbruik van 'n veevoedsel asof dit 'n misstof is, verbied; *(n)* in verband met enige ander aangeleentheid wat ingevolge hierdie Wet voorgeskryf moet word, en oor die algemeen vir die doeltreffende uitvoer van die doelstellings en oogmerke van hierdie Wet. (2) Verskillende regulasies kan kragtens hierdie artikel uitgevaardig word ten opsigte van verskillende klasse of soorte misstowwe, veevoedsel of landboumiddels 1[of veemiddels] en ten opsigte van verskillende soorte aanlegginge en verskillende klasse of groepe persone. (3) Regulasies wat kragtens hierdie artikel uitgevaardig word, kan vir oortreding daarvan of versuim om daaraan te voldoen, strawwe wat nie die maksimum strawwe soos voorgeskryf in artikel 18 1*[agtien1]* te bowe gaan nie, oplê. (4) Alvorens regulasies kragtens hierdie artikel uitgevaardig word, word sodanige regulasies deur die Minister in die *Staatskoerant* gepubliseer, tesame met 'n kennisgewing ten effekte dat daar 'n voorneme is om sodanige regulasies as regulasies kragtens hierdie artikel binne 'n bepaalde tydperk, maar minstens 4 1[vier] weke vanaf die datum van genoemde publikasie, uit te vaardig en dat belanghebbende persone uitgenodig word om besware teen of vertoë aangaande die voorgestelde regulasies voor te lê: Met dien verstande dat, indien die Minister daarna enige wysigings in die soos voormeld gepubliseerde regulasies aanvaar, as gevolg van besware of vertoë in verband daarmee voorgelê, dit nie nodig is om sodanige wysigings te publiseer voor die regulasies uiteindelik ooreenkomstig subartikel (1) uitgevaardig word nie. (5) 'n Regulasie waarby finansiële aangeleenthede betrokke is, word in oorleg met die Minister van Finansies uitgevaardig.

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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 title 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 prohibit the 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.**".

No en jaar van wet	Kort titel	Mate waarin gewysig
		Die vervanging van artikel 26 van Wet 36 van 1947. 18. Artikel 26 van Wet 36 van 1947 word hierby deur die volgende artikel vervang: "26. Hierdie Wet heet die Wet op Misstowwe, Veevoedsel en Landboumiddels, 1947.".
		Die vervanging van die lang titel van Wet 36 van 1947, soos gewysig by artikel 3 van Wet 48 van 1950 en artikel 44 van Wet 28 van 1961 en vervang by artikel 16 van Wet 60 van 1970, artikel 22 van Wet 24 van 1977 en artikel 10 van Wet 4 van 1980. 19. Die lang titel van Wet 36 van 1947 word hierby deur die volgende lang titel vervang: **"Om voorsiening te maak vir die aanstelling van 'n Registrateur van Misstowwe, Veevoedsel en Landboumiddels; vir die registrasie van misstowwe, veevoedsel, landboumiddels, steriliseringsinstallasies en plaagbeheeroperateurs; om die invoer, verkoop, verkryging, vervreemding of gebruik van misstowwe, veevoedsel en landboumiddels te reël of te verbied; om voorsiening te maak vir die aanwysing van tegniese adviseurs en ontleders; en om vir daarmee in verband staande aangeleenthede voorsiening te maak.".**

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