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REPUBLIC OF SOUTH AFRICA

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DEPARTEMENT VAN DIE EERSTE MINISTER

No. 583. 21 Maart 1979.

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

No. 17 van 1979: Wysigingswet op die Beheer van Medisyne en Verwante Stowwe, 1979.

DEPARTMENT OF THE PRIME MINISTER

No. 583. 21 March 1979.

It is hereby notified that the State President has assented to the following Act which is hereby published for general information:—

No. 17 of 1979: Medicines and Related Substances Control Amendment Act, 1979.

Act No. 17, 1979 MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT ACT, 1979.

GENERAL EXPLANATORY NOTE:

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

Words underlined with solid line indicate insertions in existing enactments.

ACT

To amend the Medicines and Related Substances Control Act, 1965, so as to define or further define certain expressions; to further regulate the constitution of the Medicines Control Council and the Medicines Control Appeal Board; to extend the provisions of the said Act to medicines intended for animals; to make new provision in relation to the labelling and advertising of medicines; to further regulate the furnishing of information regarding the registration of medicines and the cancellation of such registration; to make further provision for the control of Scheduled substances and for the authorization of inspectors, analysts, pharmacologists and pathologists to act in terms of the said Act; to further regulate the taking of and dealing with samples of medicines and Scheduled substances; and to effect a change in relation to the power to make regulations; and to provide for matters connected therewith.

(Afrikaans text signed by the State President.)
(Assented to 13 March 1979.)

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

Amendment of section 1 of Act 101 of 1965, as substituted by section 1 of Act 65 of 1974.

1. Section 1 of the Medicines and Related Substances Control Act, 1965 (hereinafter referred to as the principal Act), is hereby amended—

(a) by the insertion in subsection (1) after the definition of ''board'' of the following definition:
''''export' includes deliver or supply within the Republic for dispatch to any destination outside the Republic;'';

(b) by the insertion in subsection (1) after the definition of ''hospital'' of the following definition:
''''immediate container', in relation to a medicine or Scheduled substance, means a container which is in direct contact with the medicine or substance;'';

(c) by the substitution in subsection (1) for the definition of ''medical practitioner'' of the following definition:
''''medical practitioner' means a person registered as such under the Medical Act, and includes an intern registered under that Act and, in relation to any medicine and any Schedule 1, Schedule 2, Schedule 3 and Schedule 4 substance, a student intern

WYSIGINGSWET OP DIE BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1979. **Wet No. 17, 1979**

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.

WET

Tot wysiging van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965, ten einde sekere uitdrukkings te omskryf of nader te omskryf; die samestelling van die Medisynebeheerraad en die Appèlraad op Medisynebeheer verder te reël; die bepalings van genoemde Wet uit te brei tot medisyne bestem vir diere; nuwe voorsiening te maak met betrekking tot die etikettering en adverteer van medisyne; die verstrekking van inligting omtrent die registrasie van medisyne en die intrekking van sodanige registrasie verder te reël; verdere voorsiening te maak vir beheer oor gelyste stowwe en vir die magtiging van inspekteurs, ontleders, farmakoloë en patoloë om ingevolge genoemde Wet op te tree; die neem van monsters van medisyne en gelyste stowwe, en die wyse waarop daarmee gehandel moet word, verder te reël; en 'n verandering aan te bring met betrekking tot die bevoegdheid om regulasies uit te vaardig; en om voorsiening te maak vir aangeleenthede wat daarmee in verband staan.

(*Afrikaanse teks deur die Staatspresident geteken.*)
(*Goedgekeur op 13 Maart 1979.*)

DAAR WORD BEPAAL deur die Staatspresident, die Senaat en die Volksraad van die Republiek van Suid-Afrika, soos volg:—

Wysiging van artikel 1 van Wet 101 van 1965, soos vervang deur artikel 1 van Wet 65 van 1974.

1. Artikel 1 van die Wet op die Beheer van Medisyne en Verwante Stowwe, 1965 (hieronder die Hoofwet genoem), word hierby gewysig—

(a) deur in subartikel (1) die omskrywing van „apteker" deur die volgende omskrywing te vervang:

„'apteker' iemand wat kragtens die Wet op Aptekers, 1974, as sodanig geregistreer is, en ook 'n kwekeling-apteker, soos in daardie Wet omskryf, gedurende die twaalfde maand van die tydperk of tydperke van praktiese opleiding bedoel in artikel 20 (1) van daardie Wet;";

(b) deur na die omskrywing van „apteker" die volgende omskrywing in te voeg:

„'aptekersassistent' iemand wat kragtens die Wet op Aptekers, 1974, as sodanig geregistreer is;";

(c) deur in subartikel (1) die omskrywing van „geneesheer" deur die volgende omskrywing te vervang:

„'geneesheer' iemand wat kragtens die Wet op Geneeshere as sodanig geregistreer is, en ook 'n intern wat kragtens daardie Wet geregistreer is, en, met betrekking tot 'n medisyne en 'n Bylae 1-, Bylae 2-, Bylae 3- en Bylae 4-stof, ook 'n student-intern kragtens daardie Wet geregistreer wat soos beoog

registered under that Act who prescribes or provides the medicine or any such substance, as contemplated in section 36 (2) *(a A)* of the said Act;'';

(d) by the substitution in subsection (1) for the definition of ''medicine'' of the following definition:

'''medicine' means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

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

(b) restoring, correcting or modifying any somatic or psychic or organic function in man,

and includes any veterinary medicine;'';

(e) by the substitution in subsection (1) for the definition of ''pharmacist'' of the following definition:

'''pharmacist' means a person registered as such under the Pharmacy Act, 1974, and includes a trainee pharmacist, as defined in that Act, during the twelfth month of the period or periods of practical training referred to in section 20 (1) of that Act;'';

(f) by the insertion in subsection (1) after the definition of ''pharmacist'' of the following definition:

'''pharmacist's assistant' means a person registered as such under the Pharmacy Act, 1974;'';

(g) by the deletion in subsection (1) of the definition of ''unqualified assistant'';

(h) by the addition to subsection (1) of the following definition:

'''veterinary medicine' means any substance or mixture of substances, other than a stock remedy or farm feed to be registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), used or purporting to be suitable for use or manufactured or sold for use in connection with vertebrates, for the treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity, or for curing, correcting or modifying any somatic or organic function, or for correcting or modifying behaviour.'';

(i) by the substitution for subsection (2) of the following subsection:

''(2) A medicine **[produced either within or outside the Republic]** shall, notwithstanding the fact that its components are identical to those of any other medicine as to physical characteristics, quantity and quality, for the purposes of this Act not be regarded as being the same medicine as that other medicine if registration thereof is not applied for by the same applicant **[or if it is not presented in the same form]** as that other medicine.''; and

(j) by the substitution for subsection (3) of the following subsection:

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

in artikel 36 (2) *(a A)* van genoemde Wet die medisyne of so 'n gelyste stof voorskryf of verskaf;''.

(d) deur in subartikel (1) die omskrywing van ,,medisyne'' deur die volgende omskrywing te vervang:

,,,medisyne' enige stof of mengsel van stowwe wat gebruik word of geskik heet te wees vir gebruik of vervaardig of verkoop word vir gebruik by—

(a) die diagnose, behandeling, leniging, matiging of voorkoming van siektes, abnormale liggaamlike of geestelike toestande of die simptome daarvan by die mens; of

(b) genesing, regstelling of matiging van enige somatiese of psigiese of organiese funksie by die mens,

en ook 'n veterinêre medisyne;'';

(e) deur in subartikel (1) die omskrywing van ,,ongekwalifiseerde assistent'' te skrap;

(f) deur in subartikel (1) die volgende omskrywing na die omskrywing van ,,Minister'' in te voeg:

,,,onmiddellike houer', met betrekking tot 'n medisyne of gelyste stof, 'n houer wat in direkte aanraking met die medisyne of stof is;'';

(g) deur in subartikel (1) die volgende omskrywing na die omskrywing van ,,tandarts'' in te voeg:

,,,uitvoer' ook in die Republiek lewer of verskaf vir versending na 'n bestemming buite die Republiek;'';

(h) deur in subartikel (1) die volgende omskrywing na die omskrywing van ,,verkoop'' in te voeg:

,,,veterinêre medisyne' enige stof of mengsel van stowwe, uitgesonderd 'n veemiddel of veevoedsel wat ingevolge die Wet op Misstowwe, Veevoedsel, Landboumiddels of Veemiddels, 1947 (Wet No. 36 van 1947), geregistreer moet word, wat gebruik word of geskik heet te wees vir gebruik of vervaardig of verkoop word vir gebruik, in verband met gewerwelde diere, vir die behandeling, diagnose, voorkoming of genesing van 'n siekte, besmetting of ander ongesonde toestand, of vir die instandhouding of verbetering van gesondheid, groei, produksie of werkvermoë, of vir die genesing, regstelling of matiging van enige somatiese of organiese funksie, of vir die regstelling of matiging van gedrag;'';

(i) deur subartikel (2) deur die volgende subartikel te vervang:

,,(2) 'n Medisyne **[hetsy in of buite die Republiek geproduseer]** word by die toepassing van hierdie Wet nie geag dieselfde medisyne as ander medisyne te wees nie, al is die bestanddele daarvan wat betref fisiese eienskappe, hoeveelheid en gehalte dieselfde as dié van daardie ander medisyne, indien aansoek om registrasie daarvan nie deur dieselfde aansoeker as daardie ander medisyne gedoen is **[of dit nie in dieselfde vorm as daardie ander medisyne aangebied word]** nie.''; en

(j) deur subartikel (3) deur die volgende subartikel te vervang:

,,(3) Wanneer bepaal word of die registrasie of beskikbaarheid van 'n medisyne in die openbare belang is al dan nie, word in aanmerking geneem slegs die veiligheid, gehalte en geneeskundige doeltreffendheid daarvan met betrekking tot die uitwerking daarvan op die gesondheid van die mens of dier, na gelang van die geval.''.

Act No. 17, 1979 MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT ACT, 1979.

Amendment of section 3 of Act 101 of 1965, as amended by section 3 of Act 65 of 1974 and section 1 of Act 36 of 1977.

2. Section 3 of the principal Act is hereby amended—

(a) by the substitution for subsection (1) of the following subsection:

"(1) The council shall consist of not less than seven or more than **[fifteen]** sixteen members as may from time to time be determined by the State President."; and

(b) by the insertion in subsection (2) of the following paragraph after paragraph *(d)*:

"*(d*A*)* at least one person who shall be a veterinarian;".

Amendment of section 6 of Act 101 of 1965, as amended by section 5 of Act 65 of 1974.

3. Section 6 of the principal Act is hereby amended—

(a) by the substitution for paragraph *(b)* of subsection (1) of the following paragraph:

"*(b)* who is disqualified under the Veterinary Act, 1933, the Medical Act or the Pharmacy Act, 1974, from carrying on his profession, while so disqualified;"; and

(b) by the substitution for subsection (4) of the following subsection:

"(4) For the purposes of paragraph *(c)* of subsection (1) a medical practitioner or a pharmacist or a veterinarian shall not be deemed to have an interest in the sale of any medicine by reason only of the fact that—

(a) in the case of a medical practitioner, he sells the medicine in question in the course of carrying on his professional activities as a medical practitioner; or

(b) in the case of a pharmacist, he sells the medicine in question by retail in the course of carrying on his professional activities as a pharmacist; or

(c) in the case of a veterinarian, he sells the medicine in question in the course of carrying on his professional activities as a veterinarian.".

Amendment of section 10 of Act 101 of 1965, as substituted by section 8 of Act 65 of 1974.

4. Section 10 of the principal Act is hereby amended—

(a) by the substitution in subsection (1) for the words preceding paragraph *(a)* of the following words:

"(1) There is hereby established a board to be known as the Medicines Appeal Board, which shall consist of **[three]** four members to be appointed by the State President, of whom—";

(b) by the substitution for paragraph *(b)* of the said subsection (1) of the following paragraph:

"*(b)* one shall be a medical practitioner who has a speciality in medicine entered in the appropriate register contemplated in section **[19]** 18 of the Medical Act; **[and]**";

(c) by the insertion after paragraph *(b)* of the said subsection (1) of the following paragraph:

"*(b*A*)* one shall be a veterinarian; and"; and

(d) by the addition of the following subsection:

"(3) The member of the appeal board—

(a) referred to in subsection (1) *(b)*, shall not participate in any proceedings of the appeal board relating to any medicine which is a veterinary medicine; and

(b) referred to in subsection (1) *(b*A*)*, shall not participate in any proceedings of the appeal board relating to any medicine other than a veterinary medicine.".

Amendment of section 11 of Act 101 of 1965, as amended by section 9 of Act 65 of 1974.

5. Section 11 of the principal Act is hereby amended by the substitution for subsection (4) of the following subsection:

"(4) For the purposes of paragraph *(f)* of subsection (1) a medical practitioner or a veterinarian shall not be deemed to have an interest in the sale of any medicine by reason only of

WYSIGINGSWET OP DIE BEHEER VAN MEDISYNE EN VERWANTE STOWWE, 1979. **Wet No. 17, 1979**

2. Artikel 3 van die Hoofwet word hierby gewysig— Wysiging van artikel 3 van Wet 101 van 1965, soos gewysig deur artikel 3 van Wet 65 van 1974 en artikel 1 van Wet 36 van 1977.

(a) deur subartikel (1) deur die volgende subartikel te vervang:

„(1) Die raad bestaan uit minstens sewe en hoogstens **[vyftien]** sestien lede soos van tyd tot tyd deur die Staatspresident bepaal.''; en

(b) deur in subartikel (2) die volgende paragraaf na paragraaf *(d)* in te voeg:

„*(d*A*)* minstens een persoon wat 'n veearts moet wees;''.

3. Artikel 6 van die Hoofwet word hierby gewysig— Wysiging van artikel 6 van Wet 101 van 1965, soos gewysig deur artikel 5 van Wet 65 van 1974.

(a) deur paragraaf *(b)* van subartikel (1) deur die volgende paragraaf te vervang:

„*(b)* wat ingevolge die Veeartswet, 1933, die Wet op Geneeshere of die Wet op Aptekers, 1974, onbevoeg is om sy beroep te beoefen, terwyl hy aldus onbevoeg is;''; en

(b) deur subartikel (4) deur die volgende subartikel te vervang:

„(4) By die toepassing van paragraaf *(c)* van subartikel (1) word 'n geneesheer of 'n apteker of 'n veearts nie geag 'n belang by die verkoop van enige medisyne te hê nie bloot omrede die feit dat hy—

(a) in die geval van 'n geneesheer, die betrokke medisyne in die loop van die verrigting van sy professionele werksaamhede as 'n geneesheer, verkoop; of

(b) in die geval van 'n apteker, die betrokke medisyne by die klein maat in die loop van die verrigting van sy professionale bedrywighede as 'n apteker, verkoop; of

(c) in die geval van 'n veearts, die betrokke medisyne in die loop van die verrigting van sy professionele werksaamhede as 'n veearts, verkoop.''.

4. Artikel 10 van die Hoofwet word hierby gewysig— Wysiging van artikel 10 van Wet 101 van 1965, soos vervang in die Engelse teks deur artikel 8 van Wet 65 van 1974.

(a) deur in subartikel (1) die woorde wat paragraaf *(a)* voorafgaan deur die volgende woorde te vervang:

„(1) Hierby word 'n raad ingestel wat die Appèlraad op Medisynebeheer heet en bestaan uit **[drie]** vier lede deur die Staatspresident aangestel, van wie—'';

(b) deur paragraaf *(b)* van genoemde subartikel (1) deur die volgende paragraaf te vervang:

„*(b)* een 'n geneesheer is wat 'n spesialiteit in geneeskunde besit wat in die toepaslike in artikel **[vyftien]** 18 van die Wet op Geneeshere beoogde register ingeskryf is; **[en]**'';

(c) deur na paragraaf *(b)* van genoemde subartikel (1) die volgende paragraaf in te voeg:

„*(b*A*)* een 'n veearts is; en''; en

(d) deur die volgende subartikel by te voeg:

„(3) Die lid van die appèlraad—

(a) in subartikel (1) *(b)* bedoel, neem nie deel aan verrigtinge van die appèlraad met betrekking tot 'n medisyne wat 'n veterinêre medisyne is nie; en

(b) in subartikel (1) *(b*A*)* bedoel, neem nie deel aan verrigtinge van die appèlraad met betrekking tot 'n medisyne wat nie 'n veterinêre medisyne is nie.''.

5. Artikel 11 van die Hoofwet word hierby gewysig deur subartikel (4) deur die volgende subartikel te vervang: Wysiging van artikel 11 van Wet 101 van 1965, soos gewysig deur artikel 9 van Wet 65 van 1974.

„(4) By die toepassing van paragraaf *(f)* van subartikel (1) word 'n geneesheer of 'n veearts nie geag 'n belang by die verkoop van enige medisyne te hê bloot omrede hy die

the fact that he sells the medicine in question in the course of carrying on his professional activities as a medical practitioner or a veterinarian.''.

Amendment of section 14 of Act 101 of 1965, as substituted by section 12 of Act 65 of 1974.

6. Section 14 of the principal Act is hereby amended by the substitution for subsection (4) of the following subsection:

''(4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine compounded in the course of carrying on his professional activities by a medical practitioner or a veterinarian for a particular person or animal, as the case may be, in a quantity not greater than the quantity required for treatment as determined by the medical practitioner or veterinarian or compounded by a pharmacist for a particular person or animal in a quantity not greater than that normally required for the purpose for which it is sold or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian, 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 and has not been advertised.''.

Substitution of section 18 of Act 101 of 1965, as substituted by section 16 of Act 65 of 1974.

7. The following section is hereby substituted for section 18 of the principal Act:

''Labels and advertisements.

18. (1) No person shall sell any medicine or Scheduled substance unless the immediate container or the package in which that medicine or Scheduled substance is sold bears a label stating the prescribed particulars.

(2) No person shall advertise any medicine or Scheduled substance for sale unless such advertisement complies with the prescribed requirements.''.

Substitution of section 22 of Act 101 of 1965, as amended by section 20 of Act 65 of 1974.

8. The following section is hereby substituted for section 22 of the principal Act:

''Secretary to cause certain information to be furnished.

22. (1) The **[council shall, subject to the approval of the Secretary, in such manner as it]** Secretary shall, after consultation with the council, cause, in such manner as the Secretary considers most suitable—

(a) as soon as practicable after any medicine, other than a veterinary medicine, has been registered, **[inform]** medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine to be informed—

(i) of the name and number under which such medicine is registered and the conditions, if any, subject to which such medicine is registered;

(ii) of the therapeutic efficacy and effect of such medicine;

(iii) of the purpose for which, the circumstances under which and the manner in which such medicine should be used; and

(iv) regarding any other matter concerning such medicine which, in the opinion of the council, may be of value to them;

(b) as soon as practicable after the registration of any medicine, other than a veterinary medicine, has been cancelled in terms of section 16, **[inform]** medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine to be informed of the cancellation of such registration.

betrokke medisyne in die loop van die verrigting van sy professionele bedrywighede as 'n geneesheer of 'n veearts verkoop nie.''.

Wysiging van artikel 14 van Wet 101 van 1965, soos vervang deur artikel 12 van Wet 65 van 1974.

6. Artikel 14 van die Hoofwet word hierby gewysig deur subartikel (4) deur die volgende subartikel te vervang:

„(4) Die bepalings van subartikel (1) is nie van toepassing nie ten opsigte van die verkoop van enige medisyne wat deur 'n geneesheer of veearts in die loop van die verrigting van sy professionele bedrywighede aangemaak word vir 'n bepaalde persoon of dier, na gelang van die geval, in 'n hoeveelheid nie groter nie as die hoeveelheid nodig vir behandeling soos deur die geneesheer of veearts bepaal of deur 'n apteker aangemaak word vir 'n bepaalde persoon of dier in 'n hoeveelheid nie groter nie as dié wat normaalweg nodig is vir die doel waarvoor dit verkoop word, of in 'n hoeveelheid vir 'n bepaalde persoon of dier soos deur 'n geneesheer of tandarts of veearts, na gelang van die geval, voorgeskryf, indien sodanige medisyne nie 'n bestanddeel bevat waarvan die verkoop deur hierdie Wet verbied word of 'n bestanddeel ten opsigte waarvan 'n aansoek om registrasie van die hand gewys is nie, en nie geadverteer word of is nie.''.

Vervanging van artikel 18 van Wet 101 van 1965, soos vervang deur artikel 16 van Wet 65 van 1974.

7. Artikel 18 van die Hoofwet word hierby deur die volgende artikel vervang:

„Etikette en advertensies.

18. (1) Niemand mag medisyne of 'n gelyste stof verkoop nie tensy die onmiddellike houer of die pakket waarin daardie medisyne of gelyste stof verkoop word 'n etiket aanhet waarop die voorgeskrewe besonderhede vermeld word.

(2) Niemand mag medisyne of 'n gelyste stof vir verkoop adverteer nie, tensy bedoelde advertensie aan die voorgeskrewe vereistes voldoen.''.

Vervanging van artikel 22 van Wet 101 van 1965, soos gewysig deur artikel 20 van Wet 65 van 1974.

8. Artikel 22 van die Hoofwet word hierby deur die volgende artikel vervang:

„Sekretaris moet sekere inligting laat verstrek.

22. (1) Die **[raad moet, onderworpe aan die goedkeuring van die Sekretaris, en op die wyse wat die raad]** Sekretaris moet, na oorlegpleging met die raad, op die wyse wat die Sekretaris die geskikste ag—

(a) so spoedig doenlik nadat 'n medisyne, uitgesonderd 'n veterinêre medisyne, geregistreer is, geneeshere, tandartse, aptekers en die persoon wat aansoek om die registrasie van sodanige medisyne gedoen het, laat verwittig van—

(i) die naam en nommer waaronder sodanige medisyne geregistreer is en die voorwaardes (as daar is) waaraan dié medisyne se registrasie onderworpe gestel is;

(ii) die terapeutiese doeltreffendheid en effek van sodanige medisyne;

(iii) die doel waarvoor, die omstandighede waaronder en die wyse waarop sodanige medisyne gebruik behoort te word; en

(iv) enige ander aangeleentheid betreffende sodanige medisyne wat, na die mening van die raad, vir hulle van waarde kan wees;

(b) so spoedig doenlik nadat die registrasie van 'n medisyne, uitgesonderd 'n veterinêre medisyne, ingevolge artikel 16 ingetrek is, geneeshere, tandartse, aptekers en die persoon wat aansoek om die registrasie van sodanige medisyne gedoen het, van die intrekking van sodanige registrasie laat verwittig.

(2) The provisions of subsection (1) shall apply *mutatis mutandis* in respect of any veterinary medicine, and for the purposes of such application the reference in that subsection to medical practitioners and dentists shall be deemed to be a reference to veterinarians.''.

Amendment of section 22A of Act 101 of 1965, as inserted by section 21 of Act 65 of 1974.

9. Section 22A of the principal Act is hereby amended—

(a) by the substitution for the proviso to subsection (3) of the following proviso:

''Provided that any Schedule 1 substance shall not be sold to any person apparently under the age of sixteen years except upon a prescription issued by a medical practitioner, dentist or veterinarian and dispensed by a pharmacist, trainee pharmacist or **[unqualified]** pharmacist's assistant or by a medical practitioner or dentist or veterinarian or on a written order which discloses 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 sixteen years **[and such order shall be retained by the seller for a period of not less than six months after the relevant sale]**.'';

(b) by the substitution for subsection (4) of the following subsection:

''(4) Any Schedule 2 substance shall not be sold—

(a) by any person other than a pharmacist or a trainee pharmacist or **[unqualified]** pharmacist's assistant acting under the personal supervision of a pharmacist; and

(b) to any person apparently under the age of sixteen years except upon a prescription issued by a medical practitioner, dentist or veterinarian and dispensed by a pharmacist, trainee pharmacist or **[unqualified]** pharmacist's assistant or by a medical practitioner or dentist or veterinarian or on a written order which discloses 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 sixteen years; and

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

(c) by the substitution for paragraph *(a)* of subsection (5) of the following paragraph:

''*(a)* by any person other than a pharmacist or a trainee pharmacist or **[unqualified]** pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by a medical practitioner, dentist or veterinarian or on the verbal instructions of a medical practitioner, dentist or veterinarian who is known to such pharmacist; or'';

(d) by the substitution for paragraph *(c)* of subsection (5) of the following paragraph:

''*(c)* unless the seller, except a manufacturer of or wholesale dealer in pharmaceutical products, enters in the prescribed manner in a prescription book required to be kept in the prescribed manner, all the prescribed particulars of such sale; and'';

(e) by the substitution in paragraph *(a)* of subsection (6) for the words preceding the proviso of the following words:

(2) Die bepalings van subartikel (1) is *mutatis mutandis* ten opsigte van 'n veterinêre medisyne van toepassing, en vir die doeleindes van bedoelde toepassing word die verwysing in subartikel (1) na geneeshere en tandartse geag 'n verwysing na veeartse te wees.''.

9. Artikel 22A van die Hoofwet word hierby gewysig— Wysiging van artikel 22A van Wet 101 van 1965, soos ingevoeg deur artikel 21 van Wet 65 van 1974.

(a) deur die voorbehoudsbepaling by subartikel (3) deur die volgende voorbehoudsbepaling te vervang:

„Met dien verstande dat enige Bylae 1-stof nie aan iemand wat oënskynlik minder as sestien jaar oud is, verkoop mag word nie behalwe op 'n voorskrif uitgereik deur 'n geneesheer, tandarts of veearts en toeberei deur 'n apteker, kwekelingapteker of **[ongekwalifiseerde assistent]** aptekersassistent of deur 'n geneesheer of tandarts of veearts of op 'n skriftelike bestelling waaruit blyk vir watter gebruik bedoelde stof bestem is en waarop 'n handtekening voorkom wat aan die verkoper bekend is as die handtekening van iemand wat die verkoper ken en wat oënskynlik meer as sestien jaar oud is **[en daardie bestelling moet deur die verkoper bewaar word vir 'n tydperk van minstens ses maande na die betrokke verkoop]**.'';

(b) deur subartikel (4) deur die volgende subartikel te vervang:

„(4) 'n Bylae 2-stof mag nie verkoop word nie—

(a) deur iemand anders as 'n apteker of 'n kwekelingapteker of **[ongekwalifiseerde assistent]** aptekersassistent handelende onder die persoonlike toesig van 'n apteker; en

(b) aan iemand wat oënskynlik minder as sestien jaar oud is, behalwe op 'n voorskrif uitgereik deur 'n geneesheer, tandarts of veearts en toeberei deur 'n apteker, kwekelingapteker of **[ongekwalifiseerde assistent]** aptekersassistent of deur 'n geneesheer of tandarts of veearts of op 'n skriftelike bestelling waaruit blyk vir watter gebruik bedoelde stof bestem is en waarop 'n handtekening voorkom wat aan die verkoper bekend is as die handtekening van iemand wat die verkoper ken en wat oënskynlik meer as sestien jaar oud is; en

(c) tensy die verkoper, uitgesonderd 'n vervaardiger van of groothandelaar in farmaseutiese produkte, in 'n voorskrifboek wat op die voorgeskrewe wyse gehou moet word, al die voorgeskrewe besonderhede van bedoelde verkoop opteken.'';

(c) deur paragraaf *(a)* van subartikel (5) deur die volgende paragraaf te vervang:

„*(a)* deur iemand anders as 'n apteker of 'n kwekelingapteker of **[ongekwalifiseerde assistent]** aptekersassistent handelende onder die persoonlike toesig van 'n apteker, op 'n skriftelike voorskrif uitgereik deur 'n geneesheer, tandarts of veearts of ingevolge mondelinge opdrag van 'n geneesheer, tandarts of veearts wat aan daardie apteker bekend is; of'';

(d) deur paragraaf *(c)* van subartikel (5) deur die volgende paragraaf te vervang:

„*(c)* tensy die verkoper, uitgesonderd 'n vervaardiger van of groothandelaar in farmaseutiese produkte, in 'n voorskrifboek wat op die voorgeskrewe wyse gehou moet word, al die voorgeskrewe besonderhede van bedoelde verkoop op die voorgeskrewe wyse opteken; en'';

(e) deur in paragraaf *(a)* van subartikel (6) die woorde wat die voorbehoudsbepaling voorafgaan deur die volgende woorde te vervang:

"*(a)* by any person other than a pharmacist or a trainee pharmacist or **[unqualified]** pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription of a medical practitioner, dentist or veterinarian or on the verbal instructions of a medical practitioner, dentist or veterinarian who is known to such pharmacist;";

(f) by the substitution for paragraph *(c)* of subsection (6) of the following paragraph:

"*(c)* unless the seller, except a manufacturer of or wholesale dealer in pharmaceutical products, enters in the prescribed manner in a prescription book required to be kept in the prescribed manner, all the prescribed particulars of such sale; and";

(g) by the substitution for the first proviso to paragraph *(d)* of subsection (6) of the following proviso:

"Provided that such sale may, if the person who issued the prescription indicated thereon the number of times **[and the intervals at which]** it may be dispensed, be repeated accordingly:";

(h) by the substitution for subparagraph (i) of paragraph *(b)* of subsection (7) of the following subparagraph:

"(i) by any person other than a pharmacist or a trainee pharmacist or **[unqualified]** pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription of a medical practitioner, dentist or veterinarian; or";

(i) by the substitution for paragraph *(e)* of subsection (7) of the following paragraph:

"*(e)* The Secretary may **[on the recommendation of the council]** issue, subject to such conditions and requirements as the Secretary may **[on such recommendation]** determine, a permit to any person to acquire, possess or use any such substance, or to collect, cultivate or keep any plant or any portion thereof from which any such substance may be extracted, derived, produced or manufactured, **[or]** for scientific, research, analytical or educational purposes.";

(j) by the substitution for paragraph *(f)* of subsection (8) of the following paragraph:

"*(f)* (i) No person shall manufacture, import or export any Schedule 6 substance unless—

[(i)] *(aa)* a permit for such manufacture **[importation or exportation]** has been issued to him by the Secretary on the recommendation of the Council, or for such importation or exportation has been issued to him by the Secretary, subject to the prescribed conditions; or

[(ii)] *(bb)* a permit has been issued to him by the Secretary, **[on the recommendation of the council and]** subject to the prescribed conditions, for the cultivation or collection of plants, or any portion thereof, from which any such substance can be extracted, derived, produced or manufactured.

(ii) The Secretary shall, on the recommendation of the council, at any time withdraw any such permit if any condition on which the permit has been issued, is not complied with.";

(k) by the substitution for paragraph *(g)* of subsection (8) of the following paragraph:

"*(g)* The Secretary may **[on the recommendation of the council]** issue, subject to such conditions and

„*(a)* deur iemand anders as 'n apteker of 'n kwekeling-apteker of **[ongekwalifiseerde assistent]** aptekers-assistent handelende onder die persoonlike toesig van 'n apteker, op 'n skriftelike voorskrif van 'n geneesheer, tandarts of veearts of ingevolge mondelinge opdrag van 'n geneesheer, tandarts of veearts wat aan daardie apteker bekend is;'';

(f) deur paragraaf *(c)* van subartikel (6) deur die volgende paragraaf te vervang:

„*(c)* tensy die verkoper, uitgesonderd 'n vervaardiger van of groothandelaar in farmaseutiese produkte, in 'n voorskrifboek wat op die voorgeskrewe wyse gehou moet word, al die voorgeskrewe besonderhede van bedoelde verkoop op die voorgeskrewe wyse opteken; en'';

(g) deur die eerste voorbehoudsbepaling by paragraaf *(d)* van subartikel (6) deur die volgende voorbehoudsbepaling te vervang:

„Met dien verstande dat, indien die persoon wat die voorskrif uitgereik het, daarop aangedui het hoeveel maal **[en met watter tussenpose]** dit toeberei kan word, bedoelde verkoop dienooreenkomstig herhaal kan word:'';

(h) deur subparagraaf (i) van paragraaf *(b)* van subartikel (7) deur die volgende subparagraaf te vervang:

„(i) deur iemand anders as 'n apteker of 'n kwekeling-apteker of **[ongekwalifiseerde assistent]** aptekers-assistent handelende onder die persoonlike toesig van 'n apteker, op 'n skriftelike voorskrif van 'n geneesheer, tandarts of veearts; of'';

(i) deur paragraaf *(e)* van subartikel (7) deur die volgende paragraaf te vervang:

„*(e)* Die Sekretaris kan, **[op aanbeveling van die raad en]** onderworpe aan die voorwaardes en vereistes wat die Sekretaris **[op daardie aanbeveling]** bepaal, aan iemand 'n permit uitreik om so 'n stof te verkry, besit of gebruik, of om 'n plant of deel daarvan waaruit so 'n stof afgetrek, verkry, voortgebring of vervaardig kan word, **[of]** vir wetenskaplike, navorsings-, analitiese of opvoedkundige doeleindes in te samel, te kweek of aan te hou.'';

(j) deur paragraaf *(f)* van subartikel (8) deur die volgende paragraaf te vervang:

„*(f)* (i) Niemand mag 'n Bylae 6-stof vervaardig, invoer of uitvoer nie, tensy—

[(i)] *(aa)* 'n permit vir bedoelde vervaardiging **[invoer of uitvoer aan hom]** deur die Sekretaris op aanbeveling van die raad, of vir bedoelde invoer of uitvoer, deur die Sekretaris, aan hom **[en]** onderworpe aan die voorgeskrewe voorwaardes uitgereik is; of

[(ii)] *(bb)* 'n permit aan hom deur die Sekretaris, **[op aanbeveling van die raad en]** onderworpe aan die voorgeskrewe voorwaardes, uitgereik is vir die kweek of insamel van plante of deel daarvan waaruit so 'n stof afgetrek, verkry, voortgebring of vervaardig kan word.

(ii) Die Sekretaris moet, op aanbeveling van die raad, te eniger tyd so 'n permit intrek indien daar aan 'n voorwaarde waarop die permit uitgereik is, nie voldoen word nie.'';

(k) deur paragraaf *(g)* van subartikel (8) deur die volgende paragraaf te vervang:

„*(g)* Die Sekretaris kan, **[op aanbeveling van die raad en]** onderworpe aan die voorwaardes en vereistes

requirements as the Secretary may on **[such]** the recommendation of the council determine, a permit to any person to acquire, possess or use any Schedule 6 substance, or to collect, cultivate or keep, for scientific, research or educational purposes, any plant or any portion thereof from which any such substance can be extracted, derived, produced or manufactured.";

(l) by the insertion after paragraph *(b)* of subsection (9) of the following paragraph:

"*(b*A*)* Any seller shall, in the case of a sale as contemplated in subparagraph (i) or (ii) of paragraph *(b)*, retain the prescription or order concerned for a period of not less than three years as from the date of that sale.";

(m) by the substitution for paragraph *(f)* of subsection (9) of the following paragraph:

"*(f)* (i) No person shall manufacture, import or export any Schedule 7 substance unless—

[(i)] *(aa)* a permit for such manufacture **[importation or exportation]** has been issued to him by the Secretary on the recommendation of the council, or for such importation or exportation has been issued to him by the Secretary, subject to the prescribed conditions; or

[(ii)] *(bb)* a permit has been issued to him by the Secretary, **[on the recommendation of the council and]** subject to the prescribed conditions, for the cultivation or collection of plants, or any portion thereof, from which any such substance can be extracted, derived, produced or manufactured.

(ii) The Secretary shall, on the recommendation of the council, at any time withdraw any such permit if any condition on which the permit has been issued, is not complied with.";

(n) by the substitution for paragraph *(g)* of subsection (9) of the following paragraph:

"*(g)* The Secretary may **[on the recommendation of the council,]** issue, subject to such conditions and requirements as the Secretary may on **[such]** the recommendation of the council determine, a permit to any person to acquire, possess or use any Schedule 7 substance specified in such permit or to collect, cultivate or keep, for specified scientific, research, analytical or educational purposes, any plant or any portion thereof from which any such substance can be extracted, derived, produced or manufactured.";

(o) by the deletion of subsection (13); and

(p) by the addition to subsection (15) of the following paragraphs:

"*(c)* a pharmacist from selling in an emergency any Schedule 5, Schedule 6 or Schedule 7 substance in a quantity not greater than that required for continuous use for a period of forty-eight hours, on the verbal instructions of a medical practitioner, dentist or veterinarian who is known to such pharmacist: Provided that a medical practitioner, dentist or veterinarian who has given such verbal instructions shall within seventy-two hours after giving such instructions furnish to such pharmacist a written prescription confirming such instructions;

(d) any veterinary assistant or veterinary nurse within the meaning of the Veterinary Act, 1933 (Act No.

wat die Sekretaris op **[daardie]** die aanbeveling van die raad bepaal, aan iemand 'n permit uitreik om 'n Bylae 6-stof te verkry, besit of gebruik, of om 'n plant of deel daarvan waaruit so 'n stof afgetrek, verkry, voortgebring of vervaardig kan word, vir wetenskaplike, navorsings- of opvoedkundige doeleindes in te samel, te kweek of aan te hou.'';

(l) deur die volgende paragraaf na paragraaf *(b)* van subartikel (9) in te voeg:

„*(b A)* 'n Verkoper moet, in die geval van 'n verkoop soos in subparagraaf (i) of (ii) van paragraaf *(b)* beoog, die betrokke voorskrif of bestelling behou vir 'n tydperk van minstens drie jaar vanaf die datum van daardie verkoop.'';

(m) deur paragraaf *(f)* van subartikel (9) deur die volgende paragraaf te vervang:

„*(f)* (i) Niemand mag 'n Bylae 7-stof vervaardig, invoer of uitvoer nie, tensy—

[(i)] *(aa)* 'n permit vir bedoelde vervaardiging **[invoer of uitvoer aan hom]** deur die Sekretaris op aanbeveling van die raad, of vir bedoelde invoer of uitvoer, deur die Sekretaris, aan hom **[en]** onderworpe aan die voorgeskrewe voorwaardes uitgereik is; of

[(ii)] *(bb)* 'n permit aan hom deur die Sekretaris, **[op aanbeveling van die raad en]** onderworpe aan die voorgeskrewe voorwaardes, uitgereik is vir die kweek of insamel van plante of deel daarvan waaruit so 'n stof afgetrek, verkry, voortgebring of vervaardig kan word.

(ii) Die Sekretaris moet op aanbeveling van die raad te eniger tyd so 'n permit intrek indien daar aan 'n voorwaarde waarop die permit uitgereik is, nie voldoen word nie.'';

(n) deur paragraaf *(g)* van subartikel (9) deur die volgende paragraaf te vervang:

„*(g)* Die Sekretaris kan, **[op aanbeveling van die raad en]** onderworpe aan die voorwaardes en vereistes wat die Sekretaris op **[daardie]** die aanbeveling van die raad bepaal, aan iemand 'n permit uitreik om 'n Bylae 7-stof in die permit vermeld, te verkry, besit of gebruik, of om 'n plant of deel daarvan waaruit so 'n stof afgetrek, verkry, voortgebring of vervaardig kan word, vir bepaalde wetenskaplike, navorsings-, analitiese of opvoedkundige doeleindes in te samel, te kweek of aan te hou.'';

(o) deur subartikel (13) te skrap; en

(p) deur die volgende paragrawe by subartikel (15) te voeg:

„*(c)* 'n apteker verbied om in 'n noodgeval 'n Bylae 5-, Bylae 6- of Bylae 7-stof te verkoop in 'n hoeveelheid wat nie groter is nie as wat nodig is vir aaneenlopende gebruik vir 'n tydperk van agt-en-veertig uur ingevolge mondelinge opdrag van 'n geneesheer, tandarts of veearts wat aan daardie apteker bekend is: Met dien verstande dat 'n geneesheer, tandarts of veearts wat so 'n mondelinge opdrag gegee het, binne twee-en-sewentig uur nadat hy die opdrag gegee het, aan die apteker 'n skriftelike voorskrif, by wyse van bevestiging van bedoelde opdrag, moet verstrek;

(d) 'n veeartsenykundige assistent of veeartsenykundige verpleegster ooreenkomstig die bedoeling van die Veeartswet, 1933 (Wet No. 16 van 1933),

16 of 1933), from selling, upon a written prescription issued by a veterinarian or on the verbal instructions of a veterinarian, any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance for the treatment of any animal.''.

Amendment of section 26 of Act 101 of 1965, as amended by section 24 of Act 65 of 1974 and section 1 of Act 19 of 1976.

10. Section 26 of the principal Act is hereby amended by the substitution for subsection (1) of the following subsection:

''(1) The Secretary may **[after consultation with the council]** authorize such persons as inspectors, as he may consider necessary for the proper enforcement of this Act.''.

Substitution of section 27 of Act 101 of 1965, as substituted by section 25 of Act 65 of 1974.

11. The following section is hereby substituted for section 27 of the principal Act:

''Analysts, pharmacologists and pathologists.

27. The Secretary may **[after consultation with the council]** grant such authority to such analysts, pharmacologists and pathologists as he may consider necessary for the proper enforcement of this Act.''.

Amendment of section 28 of Act 101 of 1965, as amended by section 26 of Act 65 of 1974.

12. Section 28 of the principal Act is hereby amended—

(a) by the substitution for subsection (2) of the following subsection:

''(2) Any sample taken in terms of paragraph *(d)* of subsection (1) shall be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such medicine or Scheduled substance, or if there is no such person or if he is absent for any reason, in the presence of any other witness, **[and shall in the presence of such person or such witness be divided into three parts, each of which]** shall forthwith be **[fastened up]** packed and sealed and suitably labelled or marked in such manner as its nature may permit **[. One part]** and shall then be transmitted to an analyst, pharmacologist or pathologist together with a certificate in the prescribed forms signed by such inspector **[. The second part together with]** and a copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such medicine or Scheduled substance or his agent **[. The third part shall be retained by the inspector]**.'';

and

(b) by the substitution for subsection (3) of the following subsection:

''(3) The analyst, pharmacologist or pathologist to whom **[one part of]** a sample has been transmitted in terms of the provisions of subsection (2) shall with all convenient speed test, examine or analyse the sample delivered to him, and the result of the test, examination or analysis shall be stated in a certificate in the prescribed form.''.

Amendment of section 31 of Act 101 of 1965, as amended by section 29 of Act 65 of 1974.

13. Section 31 of the principal Act is hereby amended by the substitution for subsection (2) of the following subsection:

''(2) No prosecution shall be instituted as a result of any test, examination or analysis carried out in terms of the provisions of section 28 unless a copy of the analyst's, pharmacologist's or pathologist's certificate has, at least **[twenty-one]** fourteen days before the institution of such prosecution, been handed or transmitted by registered post to the person who is to be the accused.''.

Amendment of section 35 of Act 101 of 1965, as substituted by section 31 of Act 65 of 1974 and amended by section 3 of Act 19 of 1976.

14. Section 35 of the principal Act is hereby amended—

(a) by the insertion in subsection (1) after paragraph (xxv) of the following paragraph:

''(xxvA) as to the disposal or destruction of a Scheduled substance included in Schedule 8 in terms of section 37A, and the records which shall be kept in respect thereof;'';

verbied om op 'n skriftelike voorskrif uitgereik deur 'n veearts of ingevolge mondelinge opdrag van 'n veearts, 'n Bylae 1-, Bylae 2-, Bylae 3- of Bylae 4-stof vir die behandeling van 'n dier te verkoop.''.

10. Artikel 26 van die Hoofwet word hierby gewysig deur subartikel (1) deur die volgende subartikel te vervang: Wysiging van artikel 26 van Wet 101 van 1965, soos gewysig deur artikel 24 van Wet 65 van 1974 en artikel 1 van Wet 19 van 1976.

,,(1) Die Sekretaris kan **[na oorlegpleging met die raad]** die persone as inspekteurs magtig wat hy vir die behoorlike uitvoering van hierdie Wet nodig ag.''.

11. Artikel 27 van die Hoofwet word hierby deur die volgende artikel vervang: Vervanging van artikel 27 van Wet 101 van 1965, soos vervang deur artikel 25 van Wet 65 van 1974.

,,Ontleders, farmakoloë en patoloë.

27. Die Sekretaris kan **[na oorlegpleging met die raad]** die magtiging aan die ontleders, farmakoloë en patoloë verleen wat hy vir die behoorlike uitvoering van hierdie Wet nodig ag.''.

12. Artikel 28 van die Hoofwet word hierby gewysig— Wysiging van artikel 28 van Wet 101 van 1965, soos gewysig deur artikel 26 van Wet 65 van 1974.

(a) deur subartikel (2) deur die volgende subartikel te vervang:

,,(2) 'n Monster wat ingevolge paragraaf *(d)* van subartikel (1) geneem word, moet ooreenkomstig die voorgeskrewe metodes en in die teenwoordigheid van die persoon wat toesig het oor die medisyne of gelyste stof geneem word, of, as daar nie so 'n persoon is nie of as hy om die een of ander rede afwesig is, in die teenwoordigheid van 'n ander getuie, **[en]** word **[in die teenwoordigheid van sodanige persoon of sodanige getuie in drie dele verdeel, elk waarvan]** dadelik op die wyse wat die aard daarvan toelaat, verpak en verseël en behoorlik geëtiketteer of gemerk **[word. Een deel]** en word dan gestuur aan 'n ontleder, farmakoloog of patoloog tesame met 'n sertifikaat in die voorgeskrewe vorm wat deur die inspekteur onderteken is, **[. Die tweede deel, tesame met]** en 'n afskrif van voormelde sertifikaat word aan die eienaar of verkoper van sodanige medisyne of gelyste stof of sy agent oorhandig of per aangetekende pos gestuur **[. Die derde deel word deur die inspekteur bewaar]**.''; en

(b) deur subartikel (3) deur die volgende subartikel te vervang:

,,(3) Die ontleder, farmakoloog of patoloog aan wie **[een deel van]** 'n monster ooreenkomstig die bepalings van subartikel (2) gestuur is, moet die monster wat aan hom gelewer is so spoedig doenlik toets, ondersoek of ontleed en die resultaat van die toets, ondersoek of ontleding word aangeteken op 'n sertifikaat in die voorgeskrewe vorm.''.

13. Artikel 31 van die Hoofwet word hierby gewysig deur subartikel (2) deur die volgende subartikel te vervang— Wysiging van artikel 31 van Wet 101 van 1965, soos gewysig deur artikel 29 van Wet 65 van 1974.

,,(2) Geen vervolging mag ingestel word as gevolg van 'n toets, ondersoek of ontleding wat ingevolge die bepalings van artikel 28 uitgevoer is nie, tensy 'n afskrif van die ontleder, farmakoloog of patoloog se sertifikaat minstens **[een-en-twintig]** veertien dae voor die instelling van sodanige vervolging aan die persoon wat die beskuldigde gaan wees, oorhandig is of per aangetekende pos aan hom gestuur is.''.

14. Artikel 35 van die Hoofwet word hierby gewysig— Wysiging van artikel 35 van Wet 101 van 1965, soos vervang deur artikel 31 van Wet 65 van 1974 en gewysig deur artikel 3 van Wet 19 van 1976.

(a) deur in subartikel (1) die volgende paragraaf na paragraaf (xxv) in te voeg:

,,(xxvA) aangaande die beskikking oor of vernietiging van 'n gelyste stof wat ingevolge artikel 37A in Bylae 8 ingesluit is, en die aantekeninge wat ten opsigte daarvan gehou moet word;'';

(b) by the substitution in subsection (1) for paragraph (xxviA) of the following paragraph:

"(xxviA) as to the **[procedure to be followed if]** disposal or destruction of a Scheduled substance which has become unfit for use, and the report to be furnished in respect thereof;";

(c) by the substitution in subsection (1) for paragraph (xxvii) of the following paragraph:

"(xxvii) as to the importation, conveyance, keeping, storage, processing and packing of medicines and Scheduled substances, and the manner in which medicines and Scheduled substances shall be kept and controlled in different categories of hospitals;"; and

(d) by the substitution in subsection (1) for paragraph (xxx) of the following paragraph:

"(xxx) prescribing the fee **[(not exceeding one hundred rand)]** to be paid to the registrar in respect of the application for the registration, and in respect of the registration, of a medicine, the fee **[(not exceeding thirty rand)]** to be paid annually to the registrar in respect of the retention of the registration of a medicine and the date on which the lastmentioned fee shall be so paid;".

Substitution of long title of Act 101 of 1965, as substituted by section 37 of Act 65 of 1974.

15. The following long title is hereby substituted for the long title of the principal Act:

"ACT

To provide for the registration of medicines intended for human and for animal use, for the establishment of a Medicines Control Council, for the control of medicines and Scheduled substances and for matters incidental thereto.".

Short title.

16. This Act shall be called the Medicines and Related Substances Control Amendment Act, 1979.

(b) deur in subartikel (1) paragraaf (xxviA) deur die volgende paragraaf te vervang:

„(xxviA) aangaande die **[prosedure wat gevolg moet word indien]** beskikking oor of vernietiging van 'n gelyste stof wat onbruikbaar geword het, en die verslag wat ten opsigte daarvan verskaf moet word;'';

(c) deur in subartikel (1) paragraaf (xxvii) deur die volgende paragraaf te vervang:

„(xxvii) aangaande die invoer, vervoer, aanhouding, opslag, verwerking en verpakking van medisyne en gelyste stowwe, en die wyse waarop medisyne en gelyste stowwe in verskillende kategorieë hospitale aangehou en beheer moet word;''; en

(d) deur in subartikel (1) paragraaf (xxx) deur die volgende paragraaf te vervang:

„(xxx) wat die gelde **[(ten bedrae van hoogstens honderd rand)]** wat aan die registrateur betaal moet word ten opsigte van die aansoek om die registrasie, en ten opsigte van die registrasie, van 'n medisyne, die gelde **[(ten bedrae van hoogstens dertig rand)]** wat jaarliks aan die registrateur betaal moet word ten opsigte van die behoud van die registrasie van 'n medisyne en die datum waarop laasgenoemde gelde aldus betaal moet word, voorskryf;''.

15. Die lang titel van die Hoofwet word hierby deur die volgende lang titel vervang: Vervanging van lang titel van Wet 101 van 1965, soos vervang deur artikel 37 van Wet 65 van 1974.

„WET

Om voorsiening te maak vir die registrasie van medisyne bestem vir menslike gebruik en vir dieregebruik, vir die instelling van 'n Medisynebeheerraad, vir beheer oor medisyne en gelyste stowwe en vir aangeleenthede wat daarmee in verband staan.''.

16. Hierdie Wet heet die Wysigingswet op die Beheer van Medisyne en Verwante Stowwe, 1979. Kort titel.

GEDRUK VIR DIE STAATSDRUKKER, PRETORIA, DEUR KAAP & TRANSVAAL DRUKKERS (EDMS.) BPK., KAAPSTAD —B2252/14 700.
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