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 19 April 2009.)

ACT

To amend the Medicines and Related Substances Act, 1965, so as to provide for the establishment of the South African Health Products Regulatory Authority; for the Chief Executive Officer and staff of the Authority; for the registration of medicines, medical devices, certain foodstuffs and cosmetics; for transitional measures; and for matters connected therewith.

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

Amendment of section 1 of Act 101 of 1965, as amended by section 1 of Act 65 of 1974, section 1 of Act 17 of 1979, section 1 of Act 20 of 1981, section 1 of Act 94 of 1991, section 49 of Act 94 of 1991, section 1 of Act 49 of 1996, section 1 of Act 90 of 1997 and section 1 of Act 17 of 1979

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

(a) by the substitution for the definition of "advertisement" of the following definition:

" '**advertisement**', in relation to any **[medicine or Scheduled substance]** product, medical device or IVD, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

(a) appearing in any newspaper, magazine, pamphlet or other publication;

(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 **[medicine or Scheduled substance]** product, medical device or IVD, and '**advertise**' has a corresponding meaning;

" '**advisory committee**' means the advisory committee established in terms of section 4;";

(b) by the insertion after the definition of "**approved name**" of the following definition:

" '**Authority**' means the South African Health Products Regulatory Authority established by section 2;";

greengazette

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 19 April 2009.)

WET

Tot wysiging van die Wet op Medisyne en Verwante Stowwe, 1965, ten einde voorsiening te maak vir die instelling van die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte; vir die Hoof- Uitvoerende Beampte en personeel van die Owerheid; vir die registrasie van medisyne, mediese toestelle, sekere voedingsmiddels en skoonheidsmiddels; vir oorgangsmaatreëls; en vir aangeleenthede wat daarmee in verband staan.

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

Wysiging van artikel 1 van Wet 101 van 1965, soos gewysig deur artikel 1 van Wet 65 van 1974, artikel 1 van Wet 17 van 1979, artikel 1 van Wet 20 van 1981, artikel 1 van Wet 94 van 1991, artikel 19 van Wet 94 van 1991, artikel 1 van Wet 49 van 1996, artikel 1 van Wet 90 van 1997 en artikel 1 van Wet 17 van 1979

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

(a) deur die omskrywing van "**advertensie**" deur die volgende omskrywing te vervang:

" '**advertensie**', met betrekking tot **[medisyne of 'n gelyste stof]** 'n produk, mediese toestel of IVD, enige skriftelike, geïllustreerde, visuele of ander beskrywende stof of mondelinge verklaring of verwysing—

(a) wat in 'n nuusblad, tydskrif, pamflet of ander publikasie verskyn;

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

(c) wat op enige wyse hoegenaamd onder die aandag van lede van die publiek gebring word,

en wat bedoel is om die verkoop van daardie **[medisyne of gelyste stof]** produk, mediese toestel of IVD te bevorder, en het '**adverteer**' 'n ooreenstemmende betekenis;";

(b) deur die volgende omskrywing na die omskrywing van "**advertensie**" in te voeg:

" '**advieskomitee**' die advieskomitee ingevolge artikel 4 ingestel;";

(c) by the insertion after the definition of "certificate of registration" of the following definition:

" '**cosmetic**' means a cosmetic as defined in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), which contains a Scheduled substance;";

(d) by the deletion of the definition of "**council**";

(e) by the insertion after the definition of "**export**" of the following definition:

" '**foodstuff**' means a foodstuff as defined in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), which contains a Scheduled substance;";

(f) by the insertion after the definition of "**interchangeable multi-source medicine**" of the following definition:

" '**IVD**' *(in vitro diagnostic medical device)* means a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;";

(g) by the substitution for the definition of "medical device" of the following definition:

" '**medical device**' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article—

(a) intended by the manufacturer to be used, alone or in combination, for human beings for—

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

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

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

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means;";

(h) by the insertion after the definition of "medical device" of the following definition:

" '**medical device or IVD establishment**' means a facility used by a manufacturer, wholesaler, distributor, retailer, service provider or an importer of medical devices or IVDs for conducting business;";

(i) by the substitution 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]** humans; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in **[man]** humans, and includes any veterinary medicine";

(j) by the insertion after the definition of "**prescribed**" of the following definition:

" '**product**' means a medicine, a Scheduled substance or a cosmetic or foodstuff which contains a scheduled substance;";

(k) by the deletion of the definition of "**registrar**".

greengazette

(c) deur die volgende omskrywing na die omskrywing van "**inspekteur**" in te voeg:

" '**IVD**' ***(in vitro diagnostiese mediese toestel)*** 'n mediese toestel, ongeag of dit alleen of in kombinasie gebruik word, wat deur die vervaardiger bedoel is vir die *in vitro*-ondersoek van eksemplare verkry van die menslike liggaam uitsluitlik of hoofsaaklik om inligting te verskaf vir diagnostiese, moniterings- of versoenbaarheidsdoeleindes;";

(d) deur die omskrywing van "**mediese toestel**" deur die volgende omskrywing te vervang:

" '**mediese toestel**' enige instrument, apparaat, implement, masjien, toestel, inplant, *in vitro*-reagens of kalibreerder, sagteware, materiaal of ander soortgelyke of verwante artikel—

(a) wat deur die vervaardiger bedoel is vir gebruik, alleen of in kombinasie, vir mense by—

(i) die diagnose, voorkoming, monitering, behandeling of leniging van siektes,

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

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

(iv) die ondersteuning of onderhouding van lewe;

(v) die beheer van konsepsie;

(vi) die disinfektering van mediese toestelle; of

(vii) die verskaffing van inligting vir mediese of diagnostiese doeleindes deur middel van *in vitro*-ondersoek van eksemplare wat van die menslike liggaam verkry is; en

(b) wat nie sy primêre beoogde werking op 'n farmakologiese, immunologiese of metaboliese wyse in of op die menslike liggaam bereik nie maar wat in sy beoogde werking op so 'n wyse aangehelp kan word;";

(e) deur die volgende omskrywing na die omskrywing van **"mediese toestel"** in te voeg:

" '**mediese toestel- of IVD-inrigting**' 'n fasiliteit wat deur 'n vervaardiger, groothandelaar, verspreider, kleinhandelaar, diensverskaffer of invoerder van mediese toestelle of IVD's gebruik word om sake te doen;";

(f) deur die volgende omskrywing na die omskrywing van "**ontleder**" in te voeg:

" '**Owerheid**' die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte by artikel 2 ingestel;";

(g) deur die volgende omskrywing na die omskrywing van "**praktisyn**" in te voeg:

" '**produk**' 'n medisyne, 'n gelyste stof of 'n skoonheidsmiddel of voedingsmiddel wat 'n gelyste stof bevat;";

(h) deur die omskrywing van "**raad**" te skrap;

(i) deur die omskrywing van "**registrateur**" te skrap;

(j) deur die volgende omskrywing na die omskrywing van "**regulasie**" in te voeg:

" '**skoonheidsmiddel**' 'n skoonheidsmiddel soos omskryf ingevolge die Wet op Voedingsmiddels, Skoonheidsmiddels en Ontsmettingsmiddels, 1972 (Wet No. 54 van 1972), wat 'n gelyste stof bevat;"; en

(k) deur die volgende omskrywing na die omskrywing van "**veterinêre medisyne**" in te voeg:

" '**voedingsmiddel**' 'n voedingsmiddel soos omskryf ingevolge die Wet op Voedingsmiddels, Skoonheidsmiddels en Ontsmettingsmiddels, 1972 (Wet No. 54 van 1972), wat 'n gelyste stof bevat;".

greengazette

Substitution for section 2 of Act 101 of 1965, as substituted by section 2 of Act 65 of 1974 and amended by section 2 of Act 90 of 1997

2. The following section is hereby substituted for section 2 of the principal Act:

"**Establishment, powers and functions of South African Health Products Regulatory Authority**

2. (1) The South African Health Products Regulatory Authority is hereby established as an organ of state but outside the public service.

(2) The Authority is—

(a) a juristic person;

(b) subject to the Public Finance Management Act, 1999 (Act No. 1 of 1999); and

(c) accountable to and reports to the Minister.

(3) The Authority may exercise the powers and shall perform the functions conferred upon or assigned to it by this Act.

(4) In performing its functions, the Authority shall act without fear, favour or prejudice.".

Substitution of section 3 of 101 of 1965, as substituted by section 3 of Act 90 of 1997

3. The following section is hereby substituted for section 3 of the principal Act:

"**Chief Executive Officer and other staff of Authority**

3. (1) The Minister must appoint a suitably qualified person as the Chief Executive Officer of the Authority.

(2) A person may not be appointed as the Chief Executive Officer if such person—

(a) is an unrehabilitated insolvent;

(b) is mentally unfit; or

(c) has been convicted of an offence committed after the Constitution of the Republic of South Africa, 1993 (Act No. 200 of 1993) took effect and sentenced to imprisonment without the option of a fine.

(3) The Chief Executive Officer may be removed from office for—

(a) serious misconduct;

(b) permanent incapacity; or

(c) engaging in any activity that is reasonably capable of undermining the integrity of the Authority.

(4) The Chief Executive Officer—

(a) is appointed for a term of five years and may be reappointed for one additional term of five years;

(b) is appointed subject to the conclusion of a performance agreement with the Minister;

(c) is accountable to and reports to the Minister;

(d) is entitled to the benefits as may be determined by the Minister in consultation with the Minister for the Public Service and Administration;

(e) is responsible for the general administration of the Authority and for the carrying out of any functions assigned to the Authority by this Act and the Minister;

(f) must manage and direct the activities of the Authority;

(g) must appoint and supervise staff of the Authority; and

(h) must compile business and financial plans and reports in terms of the Public Finance Management Act, 1999 (Act No. 1 of 1999).

(5) The Chief Executive Officer shall appoint suitably qualified staff and may contract other suitably qualified persons to assist the Authority in carrying out its functions.

(6) *(a)* The Minister shall, after consultation with the Minister for Public Service and Administration, determine the structure and the human resources policy for the Authority.

greengazette

Vervanging van artikel 2 van Wet 101 van 1965, soos vervang deur artikel 2 van Wet 65 van 1974 en gewysig deur artikel 2 van Wet 90 van 1997

2. Artikel 2 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Instelling, bevoegdhede en werksaamhede van Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte**

2. (1) Die Reguleringsowerheid vir Gesondheidsprodukte word hierby ingestel as 'n staatsorgaan, maar buite die staatsdiens.

(2) Die Owerheid is—

(a) 'n regspersoon;

(b) onderhewig aan die Wet op Openbare Finansiële Bestuur, 1999 (Wet No. 1 van 1999); en

(c) aanspreeklik teenoor en doen verslag aan die Minister.

(3) Die Owerheid kan die bevoegdhede uitoefen en moet die werksaamhede verrig wat by hierdie Wet aan hom verleen of toegewys is.

(4) By die verrigting van sy werksaamhede moet die Owerheid sonder vrees, begunstiging of vooroordeel optree.".

Vervanging van artikel 3 van Wet 101 van 1965, soos vervang deur artikel 3 van Wet 90 van 1997

3. Artikel 3 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Hoof- Uitvoerende Beampte en ander personeel van Owerheid**

3. (1) Die Minister stel 'n gepas gekwalifiseerde persoon aan as die Hoof- Uitvoerende Beampte van die Owerheid.

(2) 'n Persoon mag nie as die Hoof- Uitvoerende Beampte aangestel word nie as sodanige persoon—

(a) 'n ongerehabiliteerde insolvent is;

(b) geestelik ongeskik is; of

(c) skuldig bevind is aan 'n misdryf wat gepleeg is na die inwerkingtreding van die Grondwet van die Republiek van Suid-Afrika, 1993 (Wet No. 200 van 1993), en gevonnis is tot gevangenisstraf sonder die keuse van 'n boete.

(3) Die Hoof- Uitvoerende Beampte kan uit die amp ontslaan word omrede—

(a) ernstige wangedrag;

(b) permanente ongeskiktheid; of

(c) betrokkenheid by 'n aktiwiteit wat redelikerwys die integriteit van die Owerheid kan ondermyn.

(4) Die Hoof- Uitvoerende Beampte—

(a) word vir 'n termyn van vyf jaar aangestel en kan vir een bykomende termyn van vyf jaar heraangestel word;

(b) word aangestel onderhewig aan die aangaan van 'n prestasie-ooreenkoms met die Minister;

(c) is aanspreeklik teenoor en doen verslag aan die Minister;

(d) is geregtig op die voordele wat die Minister in oorleg met die Minister vir die Staatsdiens en Administrasie bepaal;

(e) is verantwoordelik vir die algemene administrasie van die Owerheid en vir die verrigting van enige werksaamhede wat by hierdie Wet en deur die Minister aan die Owerheid toegewys word;

(f) moet die bedrywighede van die Owerheid bestuur en lei;

(g) moet personeel van die Owerheid aanstel en toesig oor hulle hou; en

(h) moet finansiële en sakeplanne en verslae opstel ingevolge die Wet op Openbare Finansiële Bestuur, 1999.

(5) Die Hoof- Uitvoerende Beampte moet gepas gekwalifiseerde personeel aanstel en kan ander gepas gekwalifiseerde persone kontrakteer om die Owerheid by te staan met die verrigting van sy werksaamhede.

(6) *(a)* Die Minister moet, na oorleg met die Minister vir die Staatsdiens en Administrasie, die struktuur en die mensehulpbronbeleid vir die Owerheid bepaal.

greengazette

(b) The human resources policy shall include a code of conduct and provisions on conflict of interests applicable to the Chief Executive Officer and the staff of the Authority.

(7) The Authority may utilise persons seconded or transferred from the public service, and such transfer must be in accordance with the Labour Relations Act, 1995 (Act No. 66 of 1995).

(8) The Chief Executive Officer and the staff of the Authority become members of the Government Employees' Pension Fund contemplated in section 2 of the Government Employees Pension Law, 1996 (Proclamation No. 21 of 1996).

(9) The Chief Executive Officer shall appoint committees, as he or she may deem necessary, to investigate and report to the Authority on any matter within its purview in terms of this Act.".

Substitution of section 4 of Act 101 of 1965

4. The following section is hereby substituted for section 4 of the principal Act:

"**Advisory committee**

4. (1) The Minister shall establish an advisory committee to advise or act as a consultative body for the Minister and the Authority on matters concerning corporate governance of the Authority.

(2) The advisory committee contemplated in subsection (1) shall consist of not more than 5 persons who shall be appointed from persons outside the Authority.

(3) The Minister shall appoint a chairperson for the advisory committee from among the members after having consulted the members.

(4) Members of the advisory committee shall—

(a) be appointed for a term not exceeding five years, which is renewable;

(b) be fit and proper persons; and

(c) have appropriate expertise, skills, knowledge or experience and the ability to perform effectively as a member.

(5) The advisory committee shall determine procedures for its meetings.

(6) An advisory committee member who has a personal or financial interest in any matter on which the advisory committee gives advice shall disclose that interest and where the advisory committee deems it necessary withdraw from the discussions.

(7) The Authority shall remunerate a member mentioned above and compensate the member for expenses, as determined by the Minister after consultation with the Minister of Finance.

(8) The advisory committee or its members shall not interfere with the powers assigned to the Chief Executive Officer or the Authority in terms of this Act in so far as those powers relate to the safety, efficacy and quality of products, medical devices or IVDs.".

Repeal of sections 5, 6, 7, 8, 9 and 12 of Act 101 of 1965

5. Sections 5, 6, 7, 8, 9 and 12 of the principal Act are hereby repealed.

Substitution of section 13 of Act 101 of 1965, as substituted by section 3 of Act 20 of 1981

6. The following section is hereby substituted for section 13 of the principal Act:

"**Registers**

13. The Chief Executive Officer shall keep separate registers for products, medical devices or IVDs; in which he or she shall record—

(a) the registration of products, medical devices or IVDs by the Authority; and

greengazette

(b) Die mensehulpbronbeleid moet insluit 'n gedragskode en bepalings rakende belangebotsings van toepassing op die Hoof- Uitvoerende Beampte en die personeel van die Owerheid.

(7) Die Owerheid kan persone gebruik wat van die staatsdiens gesekondeer of oorgeplaas is, en sodanige oorplasing moet geskied ooreenkomstig die Wet op Arbeidsverhoudinge, 1995 (Wet No. 66 van 1995).

(8) Die Hoof- Uitvoerende Beampte en die personeel van die Owerheid word lede van die Regeringswerknemerspensioenfonds bedoel in artikel 2 van die Government Employees Pension Law, 1996 (Proklamasie No. 21 van 1996).

(9) Die Hoof- Uitvoerende Beampte moet na goeddunke komitees aanstel om na enige aangeleentheid binne sy funksionele terrein ingevolge hierdie Wet ondersoek in te stel en daaroor aan die Owerheid verslag te doen.".

Vervanging van artikel 4 van Wet 101 van 1965

4. Artikel 4 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Advieskomitee**

4. (1) Die Minister moet 'n advieskomitee instel om die Minister en die Owerheid te adviseer of as 'n adviserende liggaam vir die Minister en die Owerheid op te tree oor aangeleenthede rakende korporatiewe beheer van die Owerheid.

(2) Die advieskomitee in subartikel (1) beoog, bestaan uit hoogstens vyf persone, wat aangestel word uit persone buite die Owerheid.

(3) Die Minister moet vanuit die lede 'n voorsitter vir die advieskomitee aanstel na oorleg met die lede.

(4) Lede van die advieskomitee—

(a) word aangestel vir 'n termyn van hoogstens vyf jaar, wat hernubaar is;

(b) moet geskikte en gepaste persone wees; en

(c) moet gepaste kundigheid, vaardighede, kennis of ondervinding hê en die vermoë om doeltreffend as 'n lid op te tree.

(5) Die advieskomitee moet prosedures vir sy vergaderings bepaal.

(6) 'n Lid van die advieskomitee wat 'n persoonlike of ander finansiële belang het by enige aangeleentheid waaroor die advieskomitee advies gee, moet daardie belang bekend maak en hom of haar aan die besprekings onttrek waar die advieskomitee dit nodig ag.

(7) Die Owerheid besoldig 'n lid hierbo vermeld en vergoed die lid vir uitgawes, soos deur die Minister na oorleg met die Minister van Finansies bepaal.

(8) Die advieskomitee of sy lede mag nie inmeng nie in die bevoegdhede wat ingevolge hierdie Wet aan die Hoof- Uitvoerende Beampte of die Owerheid verleen is in soverre daardie bevoegdhede betrekking het op die veiligheid, doeltreffendheid en gehalte van produkte, mediese toestelle of IVD's.".

Herroeping van artikels 5, 6, 7, 8, 9 en 12 van Wet 101 van 1965

5. Artikels 5, 6, 7, 8, 9 en 12 van die Hoofwet word hierby herroep.

Vervanging van artikel 13 van Wet 101 van 1965, soos vervang deur artikel 3 van Wet 20 van 1981

6. Artikel 13 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Registers**

13. Die Hoof- Uitvoerende Beampte moet afsonderlike registers hou vir produkte, mediese toestelle of IVD's, waarin hy moet aanteken—

(a) die registrasie van produkte, mediese toestelle of IVD's deur die Owerheid; en

greengazette

(b) such particulars in regard to the products, medical devices or IVDs and the holder of certificate of registration in respect of such products, medical devices or IVDs as are required by this Act.".

Substitution of section 14 of Act 101 of 1965, as amended by section 7 of Act 94 of 1991

7. The following section is hereby substituted for section 14 of the principal Act:

"Prohibition on the sale of [medicines] products, medical devices or IVDs which are subject to registration and are not registered

14. (1) Save as provided in this section or sections 21 and 22A, no person shall sell any **[medicine]** product, medical device or IVD which is subject to registration by virtue of a **[resolution]** declaration published in terms of subsection (2) unless it is registered.

(2) *(a)* The **[council]** Authority may from time to time **[by resolution approved by the Minister,]** determine that a **[medicine]** product, medical device or IVD, or class or category of **[medicines]** product, medical device or IVD or part of any class or category of **[medicines]** product, medical devices or IVDs mentioned in the **[resolution]** declaration, shall be subject to registration in terms of this Act.

(b) Any such **[resolution]** declaration may also relate only to **[medicines,]** products, medical devices or IVDs which were available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph *(c)* or only to **[medicines]** products, medical devices or IVDs which were not then so available.

(c) Any such **[resolution]** declaration shall be published in the *Gazette* by the **[registrar]** Chief Executive Officer and shall come into operation on the date on which it is so published.

(3) In the case of a **[medicine]** product, medical device or IVD which was available for sale in the Republic immediately prior to the date of publication in the *Gazette* of the **[resolution]** declaration by virtue of which it is subject to registration in terms of this Act, the provisions of subsection (1) shall come into operation—

(a) if no application for the registration of such **[medicine]** product, medical device or IVD is made within the period of six months immediately succeeding that date, on the expiration of that period; or

(b) if application for the registration of such **[medicine]** product, medical device or IVD is made within the said period, on the date one month after the date on which a notice in respect of such **[medicine]** product, medical device or IVD is published in the *Gazette* in terms of section **15(10)** 15(9) or section 17*(a)*.

(4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine—

(a) compounded in the course of carrying on his or her professional activities by a pharmacist, veterinarian or person who is the holder of a licence contemplated in section 22C(1)*(a)*, 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 by regulation 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 Health Professions Act, 1974, and referred to in section 22A, as the case may be,

greengazette

(b) die besonderhede rakende die produkte, mediese toestelle of IVD's en die houer van 'n registrasiesertifikaat ten opsigte van sodanige produkte, mediese toestelle of IVD's wat by hierdie Wet vereis word.".

Vervanging van artikel 14 van Wet 101 van 1965, soos gewysig deur artikel 7 van Wet 94 van 1991

7. Artikel 14 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Verbod op verkoop van [medisyne] produkte, mediese toestelle of IVD's wat aan registrasie onderhewig is en nie geregistreer is nie**

14. (1) Behoudens die bepalings van hierdie artikel of artikels 21 en 22A, mag niemand enige **[medisyne]** produk, mediese toestel of IVD wat aan registrasie onderhewig is uit hoofde van 'n **[besluit]** verklaring ingevolge subartikel (2) gepubliseer, verkoop nie tensy dit geregistreer is.

(2) *(a)* Die **[raad]** Owerheid kan van tyd tot tyd **[by besluit deur die Minister goedgekeur,]** bepaal dat 'n in die **[besluit]** verklaring vermelde **[medisyne]** produk, mediese toestel of IVD of klas of kategorie van **[medisyne]** produk, mediese toestel of IVD of gedeelte van 'n klas of kategorie van **[medisyne]** produk, mediese toestel of IVD aan registrasie ingevolge hierdie Wet onderhewig is.

(b) So 'n **[besluit]** verklaring kan ook betrekking hê slegs op **[medisyne]** produkte, mediese toestelle of IVD's wat onmiddellik voor die datum waarop dit ingevolge paragraaf *(c)* in werking tree in die Republiek vir verkoop beskikbaar was, of slegs op **[medisyne]** produkte, mediese toestelle of IVD's wat nie toe aldus beskikbaar was nie.

(c) So 'n **[besluit]** verklaring moet deur die **[registrateur]** Hoof-Uitvoerende Beampte in die *Staatskoerant* gepubliseer word en tree in werking op die datum waarop dit aldus gepubliseer word.

(3) In die geval van **[medisyne]** produkte, mediese toestelle of IVD's wat onmiddellik voor die datum van publikasie in die *Staatskoerant* van die **[besluit]** verklaring uit hoofde waarvan dit aan registrasie ingevolge hierdie Wet onderhewig is, in die Republiek vir verkoop beskikbaar was, tree die bepalings van subartikel (1) in werking—

(a) indien daar nie binne die tydperk van ses maande onmiddellik na daardie datum om registrasie van daardie **[medisyne]** produkte, mediese toestelle of IVD's aansoek gedoen word nie, by verstryking van daardie tydperk; of

(b) indien daar binne daardie tydperk om die registrasie van bedoelde **[medisyne]** produkte, mediese toestelle of IVD's aansoek gedoen word, op die datum een maand na die datum waarop 'n kennisgewing met betrekking tot die **[medisyne]** produkte, mediese toestelle of IVD's ingevolge artikel **[15(10)]** 15(9) of artikel 17*(a)* in die *Staatskoerant* gepubliseer word.

(4) Die bepalings van subartikel (1) is nie van toepassing nie ten opsigte van die verkoop van enige medisyne wat—

(a) deur 'n apteker, veearts of 'n persoon wat die houer is van 'n lisensie in artikel 22C(1)*(a)* beoog in die loop van die verrigting van sy of haar professionele bedrywighede aangemaak word vir 'n bepaalde pasiënt in 'n hoeveelheid nie groter nie as die hoeveelheid nodig vir behandeling soos deur die geneesheer, apteker, praktisyn of veearts bepaal; of

(b) deur 'n apteker aangemaak word in 'n hoeveelheid nie groter nie as wat by regulasie voorgeskryf word vir verkoop in die kleinhandel onderworpe aan die voorwaardes insgelyks voorgeskryf, of in 'n hoeveelheid vir 'n bepaalde persoon of dier soos deur 'n geneesheer of tandarts of veearts of praktisyn of 'n verpleegkundige of ander persoon wat kragtens die Wet op Gesondheidsberoepe, 1974, geregistreer is en in artikel 22A bedoel, na gelang van die geval, voorgeskryf,

greengazette

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: Provided that the active components of such medicine appear in another medicine which has been registered under this Act.".

Substitution of section 15 of Act 101 of 1965, as substituted by section 9 of Act 90 of 1997

8. The following section is hereby substituted for section 15 of the principal Act:

"Registration of products, medical devices or IVDs

15. (1) Every application for the registration of a product, medical device or IVD shall be submitted to the Chief Executive Officer in the prescribed form and shall be accompanied by—

(a) the prescribed particulars;

(b) samples of the relevant products;

(c) where practicable, samples of medical devices or IVDs; and

(d) the prescribed registration fee.

(2) As soon as possible after receipt by the Chief Executive Officer of an application contemplated in subsection (1), he or she shall inform the applicant in writing that the application is being considered.

(3) *(a)* If after consideration of any such application and after any investigation or enquiry which it may consider necessary the Authority is satisfied that the product, medical device or IVD in question—

(i) is suitable for the purpose for which it is intended;

(ii) complies with the prescribed requirements;

(iii) is safe and of good quality; and

(iv) in the case of products, also efficacious,

the Authority shall issue the applicant with a certificate of registration to that effect.

(b) If the Authority is not satisfied as contemplated in paragraph *(a)*, it shall cause the applicant to be notified in writing of the reasons why it is not so satisfied and cause the applicant to be informed that he or she may within a period of 30 days after the date of the notification furnish the Chief Executive Officer with his or her comments on the Authority's reasons for not being so satisfied.

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

(4) Every product, medical device or IVD shall be registered under such name as the Authority may approve.

(5) The Chief Executive Officer shall allocate to every product, medical device or IVD registered under this Act a registration number which shall be recorded in the register opposite the name of such product, medical device or IVD and which shall be stated in the certificate of registration issued in respect of such product, medical device or IVD.

(6) Any registration under this section—

(a) may be made subject to such conditions as may be determined by the Authority; and

(b) shall in the case of medicines, be valid for a period of five years.

(7) No condition shall be imposed under subsection (6) whereby the sale of the medicine in question by any person other than a pharmacist is prohibited or until after the applicant has in writing been notified by the Chief Executive Officer that the imposition of such condition is contemplated and invited to submit written representations to the Authority in regard to the matter.

(8) If no such representations are lodged by the applicant concerned within a period of 30 days after the receipt by him or her of any notification

greengazette

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: Met dien verstande dat die aktiewe bestanddele van sodanige medisyne voorkom in 'n ander medisyne wat kragtens hierdie Wet geregistreer is.".

Vervanging van artikel 15 van Wet 101 van 1965, soos vervang by artikel 9 van Wet 90 van 1997

8. Artikel 15 van die Hoofwet word hierby deur die volgende artikel vervang:

"Registrasie van produkte, mediese toestelle of IVD's

15. (1) Elke aansoek om die registrasie van 'n produk, mediese toestel of IVD moet in die voorgeskrewe vorm by die Hoof- Uitvoerende Beampte ingedien word en moet vergesel gaan van—

(a) die voorgeskrewe besonderhede;

(b) monsters van die betrokke produkte;

(c) waar doenlik, monsters van die mediese toestelle of IVD's; en

(d) die voorgeskrewe registrasiegeld.

(2) So spoedig moontlik na ontvangs deur die Hoof- Uitvoerende Beampte van 'n aansoek in subartikel (1) beoog, moet hy of sy die applikant skriftelik in kennis stel dat die aansoek oorweeg word.

(3) *(a)* Indien die Owerheid na oorweging van enige sodanige aansoek en na 'n ondersoek of navraag wat hy nodig ag, oortuig is dat die betrokke produk, mediese toestel of IVD—

(i) geskik is vir die doel waarvoor dit bestem is;

(ii) aan die voorgeskrewe vereistes voldoen;

(iii) veilig en van goeie gehalte is; en

(iv) in die geval van produkte ook doeltreffend is,

moet die Owerheid die applikant voorsien van 'n registrasiesertifikaat te dien effekte.

(b) Indien die Owerheid nie oortuig is nie soos in paragraaf *(a)* beoog, laat hy die applikant skriftelik in kennis stel van die redes waarom hy nie aldus oortuig is nie en laat hy die applikant in kennis stel dat hy of sy binne 'n tydperk van 30 dae na die datum van die kennisgewing die Hoof- Uitvoerende Beampte kan voorsien van sy of haar opmerkings op die Owerheid se redes waarom hy nie aldus oortuig is nie.

(c) Indien geen sodanige opmerkings deur die applikant binne die genoemde tydperk voorgelê word nie, of indien die Owerheid na oorweging van enige opmerking wat aldus voorgelê is, steeds nie aldus oortuig is nie, moet hy nie die registrasiesertifikaat uitreik nie.

(4) Elke produk, mediese toestel of IVD word geregistreer onder die naam wat die Owerheid goedkeur.

(5) Die Hoof- Uitvoerende Beampte moet aan elke produk, mediese toestel of IVD wat kragtens hierdie Wet geregistreer word 'n registrasienommer toewys wat in die register aangeteken moet word teenoor die naam van sodanige produk, mediese toestel of IVD en wat vermeld moet word in die registrasiesertifikaat wat ten opsigte van sodanige produk, mediese toestel of IVD uitgereik word.

(6) 'n Registrasie kragtens hierdie artikel—

(a) kan gedoen word onderhewig aan die voorwaardes wat die Owerheid bepaal; en

(b) is vir 'n tydperk van vyf jaar geldig in die geval van medisyne.

(7) Geen voorwaarde word ingevolge subartikel (6) opgelê nie waarby die verkoop van die betrokke medisyne deur iemand anders as 'n apteker verbied word of voordat die applikant skriftelik deur die Hoof- Uitvoerende Beampte in kennis gestel is dat die oplegging van bedoelde voorwaarde beoog word en uitgenooi is om skriftelike vertoë in verband met die saak aan die Owerheid voor te lê.

(8) Indien sodanige vertoë nie binne 'n tydperk van 30 dae nadat hy of sy 'n in subartikel (7) bedoelde kennisgewing ontvang het deur die betrokke

greengazette

referred to in subsection (7), or if after consideration of any such representations the Authority is still of the opinion that the condition in question should be imposed, the Authority shall register the product, medical device or IVD concerned subject to the said condition.

(9) Notice of the rejection of an application for registration under this section in respect of a product, medical device or IVD referred to in subsection (3) of section 14 shall be given in the *Gazette* by the Chief Executive Officer.

(10) The Chief Executive Officer shall as soon as possible after the date of expiry of the appropriate period referred to in section 14(3) publish in the *Gazette* the prescribed particulars in respect of all applications for registration received by him or her prior to such date.

Substitution of section 15A of Act 101 of 1965

9. The following section is hereby substituted for section 15A of the principal Act:

"**Amendment of entries in register**

15A. (1) The entry made in the register in respect of any product, medical device or IVD may on application by the holder of a certificate of registration issued in respect of such product, medical device or IVD be amended by the Chief Executive Officer.

(2) An application for the amendment of an entry in the register shall be made to the Chief Executive Officer in the prescribed form and shall be accompanied by the prescribed application fee.

(3) The Chief Executive Officer may, if necessary, cancel the existing registration in respect of such product, medical device or IVD and issue a new certificate of registration.".

Substitution of section 15B of Act 101 of 1965

10. The following section is hereby substituted for section 15B of the principal Act:

"**Transfer of certificate of registration**

15B. (1) A certificate of registration may with the approval of the Chief Executive Officer be transferred by the holder thereof to any other person.

(2) An application for approval of the transfer of a certificate of registration shall be made to the Chief Executive Officer on the prescribed form and shall be accompanied by the certificate of registration in question and the prescribed application fee.

(3) If the Chief Executive Officer grants any application submitted to him or her in terms of subsection (2), the Chief Executive Officer shall make the necessary entries in the register relating to the person to whom the certificate of registration is transferred, cancel the existing certificate of registration and issue a new one in the prescribed form to such person.".

Amendment of section 15C of Act 101 of 1965

11. Section 15C of the principal Act is hereby amended by the substitution for paragraph *(b)* of the following paragraph:

"*(b)* prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the **[council]** Authority in the prescribed manner, may be imported;".

greengazette

applikant ingedien word nie, of indien die Owerheid na oorweging van sodanige vertoë nog van oordeel is dat die betrokke voorwaarde opgelê behoort te word, registreer die Owerheid die betrokke produk, mediese toestel of IVD behoudens genoemde voorwaarde.

(9) Die Hoof- Uitvoerende Beampte moet in die *Staatskoerant* kennis gee van die verwerping van 'n aansoek om registrasie ingevolge hierdie artikel ten opsigte van 'n produk, mediese toestel of IVD in subartikel (3) of (4) bedoel.

(10) Die Hoof- Uitvoerende Beampte moet so spoedig moontlik na die datum van verstryking van die toepaslike tydperk in artikel 14(3) bedoel, die voorgeskrewe besonderhede ten opsigte van alle aansoeke om registrasie wat hy of sy voor daardie datum ontvang het, in die *Staatskoerant* publiseer.".

Vervanging van artikel 15A van Wet 101 van 1965

9. Artikel 15A van die Hoofwet word hierby deur die volgende artikel vervang:

"**Wysiging van inskrywings in register**

15A. (1) Die inskrywing wat in die register met betrekking tot enige produk, mediese toestel of IVD gedoen is, kan op aansoek van die houer van 'n registrasiesertifikaat wat ten opsigte van daardie produk, mediese toestel of IVD uitgereik is, deur die Hoof- Uitvoerende Beampte gewysig word.

(2) 'n Aansoek om die wysiging van 'n inskrywing in die register word by die Hoof- Uitvoerende Beampte op die voorgeskrewe vorm gedoen en gaan vergesel van die voorgeskrewe aansoekgeld.

(3) Die Hoof- Uitvoerende Beampte kan, indien nodig, die bestaande registrasiesertifikaat ten opsigte van daardie produk, mediese toestel of IVD rojeer en 'n nuwe registrasiesertifikaat uitreik.".

Vervanging van artikel 15B van Wet 101 van 1965

10. Artikel 15B van die Hoofwet word hierby deur die volgende artikel vervang:

"**Oordrag van registrasiesertifikaat**

15B. (1) 'n Registrasiesertifikaat kan met die goedkeuring van die Hoof-Uitvoerende Beampte deur die houer daarvan aan iemand anders oorgedra word.

(2) Aansoek om goedkeuring van die oordrag van 'n registrasiesertifikaat word by die Hoof- Uitvoerende Beampte op die voorgeskrewe vorm gedoen en gaan vergesel van die betrokke registrasiesertifikaat en die voorgeskrewe aansoekgelde.

(3) Indien die Hoof- Uitvoerende Beampte 'n aansoek ingevolge subartikel (2) aan hom of haar voorgelê, toestaan, moet die Hoof-Uitvoerende Beampte die nodige inskrywings betreffende die persoon aan wie die registrasiesertifikaat oorgedra word in die register aanteken, die bestaande registrasiesertifikaat rojeer en 'n nuwe registrasiesertifikaat op die voorgeskrewe vorm aan daardie persoon uitreik.".

Wysiging van artikel 15C van Wet 101 van 1965

11. Artikel 15C van die Hoofwet word hierby gewysig deur paragraaf *(b)* deur die volgende paragraaf te vervang:

"*(b)* die voorwaardes voorskryf waarop 'n medisyne wat 'n identiese samestelling het, aan dieselfde kwaliteitstandaard voldoen en bedoel is om dieselfde handelsnaam te hê as dié van 'n ander medisyne wat reeds in die Republiek geregistreer is, maar wat deur iemand anders as die houer van die registrasiesertifikaat van die reeds geregistreerde medisyne ingevoer word en wat kom van enige vervaardigingsperseel van die oorspronklike vervaardiger soos deur die **[raad]** Owerheid op die voorgeskrewe wyse goedgekeur, ingevoer kan word;".

greengazette

Substitution of section 16 of Act 101 of 1965, as amended by section 14 of Act 65 of 1974 and section 4 of Act 20 of 1981

12. The following section is hereby substituted for section 16 of the principal Act:

"**Cancellation of registration**

16. (1) If the Authority—

(a) is of the opinion that a holder of a certificate of registration has failed to comply with any condition subject to which any product, medical device or IVD was registered; or

(b) is of the opinion that any product, medical device or IVD does not comply with any prescribed requirement;

the Authority shall cause notice in writing to be given accordingly by the Chief Executive Officer to the holder of the certificate of registration issued in respect of that product, medical device or IVD.

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

(3) If no such comments are so submitted, or if after consideration of any comments so submitted the Authority is of the opinion that the registration of the product, medical device or IVD in question should be cancelled, the Authority may cancel the registration thereof.

(4) If the person who is the holder of the certificate of registration issued in respect of any product, medical device or IVD fails to pay the prescribed annual fee in respect of the retention of the registration of that product, medical device or IVD before or on the prescribed date or such later date as the Chief Executive Officer may determine on application by that person, the Chief Executive Officer shall cancel the registration of that product, medical device or IVD.".

Substitution of section 17 of Act 101 of 1965, as substituted by section 5 of Act 20 of 1981

13. The following section is hereby substituted for section 17 of the principal Act:

"**Notification of registration or cancellation thereof**

17. The Chief Executive Officer shall give notice in the *Gazette* of the registration or cancellation of registration of any product, medical device or IVD in terms of this Act, and shall in such notice specify—

(a) in the case of registration of any product, medical device or IVD, the name under which such product, medical device or IVD is registered, the active components of such product, if any, the name of the person who applied for registration of such product, medical device or IVD, the number allocated to it in terms of section 15 and the conditions (if any) subject to which it is registered;

(b) in the case of a cancellation of the registration, the name under which such product, medical device or IVD was registered, the name of the holder of the certificate of registration issued in respect of such product, medical device or IVD and the number which was allocated to it in terms of section 15.".

greengazette

Vervanging van artikel 16 van Wet 101 van 1965, soos gewysig deur artikel 14 van Wet 65 van 1974 en artikel 4 van Wet 20 van 1981

12. Artikel 16 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Intrekking van registrasie**

16. (1) Indien die Owerheid—

(a) van oordeel is dat 'n houer van 'n registrasiesertifikaat versuim het om te voldoen aan 'n voorwaarde onderworpe waaraan 'n produk, mediese toestel of IVD geregistreer is; of

(b) van oordeel is dat 'n produk, mediese toestel of IVD nie aan 'n voorgeskrewe vereiste voldoen nie,

laat die Owerheid skriftelik dienooreenkomstig kennis gee deur die Hoof-Uitvoerende Beampte aan die houer van die registrasiesertifikaat wat ten opsigte van daardie produk, mediese toestel of IVD uitgereik is.

(2) So 'n kennisgewing moet die gronde vermeld waarop die Owerheid se oordeel berus en moet aandui dat die persoon aan wie dit gerig is binne een maand na ontvangs daarvan enige opmerkings by die Hoof-Uitvoerende Beampte kan indien wat hy of sy in verband met die saak wil voorlê.

(3) Indien geen opmerkings aldus ingedien word nie of indien die Owerheid na oorweging van enige aldus ingediende opmerkings van oordeel is dat die registrasie van die betrokke produk, mediese toestel of IVD ingetrek behoort te word, kan die Owerheid die registrasie daarvan intrek.

(4) Indien die persoon wat die houer is van die registrasiesertifikaat wat ten opsigte van 'n produk, mediese toestel of IVD uitgereik is, versuim om die voorgeskrewe jaarlikse geld ten opsigte van die behoud van die registrasie van daardie produk, mediese toestel of IVD te betaal voor of op die voorgeskrewe datum of die latere datum wat die Hoof- Uitvoerende Beampte op aansoek van daardie persoon bepaal, trek die Hoof-Uitvoerende Beampte die registrasie van daardie produk, mediese toestel of IVD in.".

Vervanging van artikel 17 van Wet 101 van 1965, soos vervang deur artikel 5 van Wet 20 van 1981

13. Artikel 17 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Bekendmaking van registrasie of intrekking van registrasie**

17. Die Hoof- Uitvoerende Beampte moet in die *Staatskoerant* kennis gee van die registrasie of intrekking van die registrasie van enige produk, mediese toestel of IVD ingevolge hierdie Wet, en moet in sodanige kennisgewing vermeld—

(a) in die geval van 'n registrasie van 'n produk, mediese toestel of IVD, die naam waaronder sodanige produk, mediese toestel of IVD geregistreer is, die aktiewe bestanddele van sodanige produk, as daar is, die naam van die persoon wat aansoek om die registrasie van sodanige produk, mediese toestel of IVD gedoen het, die nommer daaraan toegewys ingevolge artikel 15 en die voorwaardes (as daar is) waaraan die registrasie onderworpe gestel is;

(b) in die geval van 'n intrekking van die registrasie, die naam waaronder sodanige produk, mediese toestel of IVD geregistreer was, die naam van die houer van die registrasiesertifikaat wat ten opsigte van sodanige produk, mediese toestel of IVD uitgereik is, en die nommer wat ingevolge artikel 15 daaraan toegewys is.".

greengazette

Substitution of section 18 of Act 101 of 1965, as substituted by section 7 of Act 17 of 1979 and amended by section 11 of Act 90 of 1997

14. 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]** product unless the immediate container or the package in which that **[medicine or Scheduled substance]** product is sold bears a label stating the prescribed particulars.

(2) No person shall advertise any **[medicine or Scheduled substance]** product, medical device or IVD for sale unless such advertisement complies with the prescribed requirements.

(3) The label referred to in subsection (1) shall be approved by the **[council]** Authority.

(4) The **[council]** Authority may authorize a deviation from the prescribed format and contents of any label.

(5) The Minister may prescribe additional requirements for the labelling of **[medicines]** products, medical devices or IVDs.".

Substitution of section 18A of Act 101 of 1965

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

"**Bonusing**

18A. (1) No person shall supply any product, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.

(2) Notwithstanding subsection (1), the Minister may prescribe acceptable and prohibited acts in relation to subsection (1).".

Substitution of section 18B of Act 101 of 1965

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

"**Sampling of products, medical devices or IVDs**

18B. (1) No person shall sample any product, medical devices or IVD.

(2) Use of products, medical devices or IVDs for exhibition or appraisal purposes shall be as prescribed.

(3) For the purposes of this section 'sample' means the free supply of products, medical devices or IVDs by a device or IVD establishment, manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974 (Act No. 56 of 1974), or any professional or person authorized to use the device.".

Substitution of section 18C of Act 101 of 1965

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

"**Marketing of products, medical devices or IVDs**

18C. The Minister shall, after consultation with the relevant industries and other stakeholders, make regulations relating to the marketing of products, medical devices or IVDs and such regulations shall also provide for Codes of Practice for relevant industries.".

greengazette

Vervanging van artikel 18 van Wet 101 van 1965, soos vervang deur artikel 7 van Wet 17 van 1979 en gewysig deur artikel 11 van Wet 90 van 1997

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

"**Etikette en advertensies**

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

(2) Niemand mag **[medisyne of 'n gelyste stof]** 'n produk, mediese toestel of IVD vir verkoop adverteer nie, tensy bedoelde advertensie aan die voorgeskrewe vereistes voldoen.

(3) 'n Etiket in subartikel (1) bedoel, moet deur die **[raad]** Owerheid goedgekeur word.

(4) Die **[raad]** Owerheid kan 'n afwyking van die voorgeskrewe vorm en inhoud van 'n etiket magtig.

(5) Die Minister kan addisionele vereistes vir die etikettering van **[medisyne]** produkte, mediese toestelle of IVD's voorskryf.".

Vervanging van artikel 18A van Wet 101 van 1965

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

"**Bonusgewing**

18A. (1) Niemand mag 'n produk, mediese toestel of IVD ooreenkomstig 'n bonusstelsel, kortingstelsel of enige ander aansporingskema verskaf nie.

(2) Ondanks subartikel (1) kan die Minister aanvaarbare en verbode handelinge met betrekking tot subartikel (1) voorskryf.".

Vervanging van artikel 18B van Wet 101 van 1965

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

"**Verskaffing van monsters van produkte, mediese toestelle of IVD's**

18B. (1) Niemand mag enige monsters van produkte, mediese toestelle of IVD's verskaf nie.

(2) Die gebruik van produkte, mediese toestelle of IVD's vir vertoon- of beoordelingsdoeleindes is soos voorgeskryf.

(3) By die toepassing van hierdie artikel beteken 'monsters verskaf' die gratis voorsiening van produkte, mediese toestelle of IVD's deur 'n mediese toestel- of IVD-inrigting, vervaardiger of groothandelaar of sy agent aan 'n apteker, geneesheer, tandarts, veearts, praktisyn, verpleegkundige of ander persoon wat kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), geregistreer is, of enige professionele persoon of persoon wat gemagtig is om die toestel te gebruik.".

Vervanging van artikel 18C van Wet 101 van 1965

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

"**Bemarking van produkte, mediese toestelle of IVD's**

18C. Die Minister moet, na oorleg met die betrokke bedrywe en ander belanghebbers, regulasies met betrekking tot die bemarking van produkte, mediese toestelle of IVD's uitvaardig, en sodanige regulasies moet ook voorsiening maak vir afdwingbare praktykkodes vir die betrokke bedrywe.".

greengazette

Substitution of section 19 of Act 101 of 1965, as amended by section 17 of Act 65 of 1974

18. The following section is hereby substituted for section 19 of the principal Act:

"**Prohibition on sale of [medicine] products, medical devices or IVDs which do not comply with prescribed requirements and furnishing of information regarding [medicines] products, medical devices or IVDs to the [council] Authority**

19. (1) No person shall sell any **[medicine]** product, medical device or IVD unless it complies with the prescribed requirements.

(2) The **[council]** Authority may by notice in writing require any person who manufactures or sells **[medicines]** products, medical devices or IVDs or administers or prescribes any medicine or on whose direction any medicine is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his or her possession or which such person is in a position to obtain regarding such **[medicine or]** product, medical device or IVD.

(3) The **[council]** Authority may, if so requested by any person to whom a notice under subsection (2) is addressed, extend the period stipulated in such notice.".

Substitution of section 20 of Act 101 of 1965, as amended by section 18 of Act 65 of 1974

19. The following section is hereby substituted for section 20 of the principal Act:

"**Publication or distribution of false advertisements concerning [medicines] products, medical devices or IVDs**

20. (1) No person shall—

(a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any **[medicine]** product, medical device or IVD; or

(b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any **[medicine]** product is other than that stated by the **[council]** Authority in terms of sub-paragraph (ii) of paragraph *(a)* of section twenty-two or state or suggest that any **[medicine]** product, medical device or IVD should be used for a purpose or under circumstances or manner other than that stated by the **[council]** Authority in terms of subparagraph (iii) of paragraph *(a)* of that section.

(2) It shall be a sufficient defence in any prosecution for an offence under paragraph *(a)* of sub-section (1) if it is proved to the satisfaction of the court that the accused, not being a person selling the **[medicine]** product, medical device or IVD to which the false or misleading advertisement which is the subject of the prosecution relates, did not know, and could not reasonably be expected to have known, that the advertisement was in any respect false or misleading **[, unless it is proved that the accused failed on demand by the registrar or an inspector or a member of the South African Police to furnish the name and address of the person at whose instance the advertisement was published, distributed or so brought to the notice of the public]**.".

greengazette

Vervanging van artikel 19 van Wet 101 van 1965, soos gewysig deur artikel 17 van Wet 65 van 1974

18. Artikel 19 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Verbod op verkoop van [medisyne] produkte, mediese toestelle of IVD's wat nie aan voorgeskrewe vereistes voldoen nie en verskaffing van inligting oor [medisyne] produkte, mediese toestelle of IVD's aan die [raad] Owerheid**

19. (1) Niemand mag 'n **[medisyne]** produk, mediese toestel of IVD verkoop nie tensy dit aan die voorgeskrewe vereistes voldoen.

(2) Die **[raad]** Owerheid kan by skriftelike kennisgewing enigiemand wat 'n **[medisyne]** produk, mediese toestel of IVD vervaardig of verkoop of 'n medisyne toedien of voorskryf of op wie se lasgewing 'n medisyne toegedien word, gelas om binne 'n tydperk in so 'n kennisgewing bepaal, aan die **[raad]** Owerheid inligting oor sodanige **[medisyne]** produk, mediese toestel of IVD te verskaf wat so 'n persoon in sy of haar besit het of wat hy of sy in staat is om te verkry.

(3) Die **[raad]** Owerheid kan, indien hy daarom versoek word deur iemand aan wie 'n kennisgewing ingevolge subartikel (2) gerig is, die tydperk verleng wat in die kennisgewing bepaal word.".

Vervanging van artikel 20 van Wet 101 van 1965, soos gewysig deur artikel 18 van Wet 65 van 1974

19. Artikel 20 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Publikasie of verspreiding van vals advertensies betreffende [medisyne] produkte, mediese toestelle of IVD's**

20. (1) Niemand mag—

(a) 'n valse of misleidende advertensie betreffende 'n **[medisyne]** produk, mediese toestel of IVD publiseer of versprei of op enige ander wyse hoegenaamd tot die kennis van die publiek bring nie, of bewerkstellig of toelaat dat so 'n advertensie gepubliseer of versprei of aldus tot die kennis van die publiek gebring word nie; of

(b) in 'n advertensie 'n bewering maak ten effekte dat die terapeutiese doeltreffendheid en effek van 'n **[medisyne]** produk, mediese toestel of IVD anders is as dié wat ingevolge subparagraaf (ii) van paragraaf *(a)* van artikel *twee-en-twintig* deur die **[raad]** Owerheid vermeld is nie of verklaar of aan die hand doen dat 'n **[medisyne]** produk, mediese toestel of IVD gebruik behoort te word vir 'n ander doel of onder ander omstandighede of op 'n ander wyse as dié wat ingevolge subparagraaf (iii) van paragraaf *(a)* van daardie artikel deur die **[raad]** Owerheid vermeld is nie.

(2) Dit is 'n voldoende verweer by enige vervolging weens 'n misdryf ingevolge paragraaf *(a)* van subartikel (1) as daar tot die oortuiging van die hof bewys word dat die beskuldigde, indien hy of sy nie iemand is nie wat die **[medisyne]** produk, mediese toestel of IVD verkoop waarop die valse of misleidende advertensie, wat die onderwerp van die vervolging uitmaak, betrekking het, nie geweet het nie, en daar nie redelikerwys van hom of haar verwag kan word om te geweet het nie, dat die advertensie in enige opsig vals of misleidend was **[, tensy bewys word dat die beskuldigde versuim het om op versoek van die registrateur of 'n inspekteur of 'n lid van die Suid-Afrikaanse Polisie die naam en adres te verstrek van die persoon op wie se versoek die advertensie gepubliseer, versprei of aldus tot die kennis van die publiek gebring is]**.".

greengazette

Substitution of section 21 of Act 101 of 1965, as amended section 6 of Act 20 of 1981

20. The following section is hereby substituted for section 21 of the principal Act:

"**Authority may authorize sale of unregistered products, medical devices or IVDs for certain purposes**

21. (1) The Authority may in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of any particular product, medical device or IVD which is not registered.

(2) Any product, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

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

Substitution of section 22 of Act 101 of 1965, as amended by section 6 of Act 20 of 1981

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

"**[Director-General] Authority to cause certain information to be furnished**

22. (1) **[The Director-General shall after consultation with the council,]** The Chief Executive Officer shall cause, in such manner as **[the Director-General]** he or she considers most suitable—

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

(i) of the name and number under which such **[medicine]** product, medical device or IVD is registered and the conditions, if any, subject to which such **[medicine]** product, medical device or IVD is registered;

(ii) of the therapeutic efficacy and effect of such **[medicine]** product;

(iii) of the purpose for which, the circumstances under which and the manner in which such **[medicine]** product, medical device or IVD should be used; and

(iv) regarding any other matter concerning such **[medicine]** product, medical device or IVD which, in the opinion of the **[council]** Chief Executive Officer, may be of value to them;

(b) as soon as practicable after the registration of any **[medicine]** product, medical device or IVD, other than a veterinary medicine, has been cancelled in terms of section 16, medical practitioners, dentists, pharmacists, the public in general and the holder of the certificate of registration issued in respect of such **[medicine]** product, medical device or IVD to be informed of the cancellation of such registration.

(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 substituted by section 13 of Act 90 of 1997 and amended by section 5 of Act 59 of 2002

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

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

greengazette

Vervanging van artikel 21 van Wet 101 van 1965, soos gewysig deur artikel 6 van Wet 20 van 1981

20. Artikel 21 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Owerheid kan verkoop van ongeregistreerde produkte, mediese toestelle of IVD's vir sekere doeleindes magtig**

21. (1) Die Owerheid kan enige persoon skriftelik magtig om gedurende 'n bepaalde tydperk 'n bepaalde hoeveelheid van 'n bepaalde produk, mediese toestel of IVD wat nie geregistreer is nie, aan 'n bepaalde persoon of inrigting te verkoop.

(2) 'n Produk, mediese toestel of IVD wat uit hoofde van 'n kragtens subartikel (1) verleende magtiging verkoop word, kan gebruik word vir die doeleindes en op die wyse en gedurende die tydperk wat die Owerheid skriftelik bepaal.

(3) Die Owerheid kan te eniger tyd by skriftelike kennisgewing 'n magtiging wat ingevolge subartikel (1) verleen is, intrek, indien daar nie aan 'n bepaling wat ingevolge subartikel (2) gemaak is, gevolg gegee word nie.".

Vervanging van artikel 22 van Wet 101 van 1965, soos gewysig deur artikel 6 van Wet 20 van 1981

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

"**[Direkteur-generaal] Owerheid moet sekere inligting laat verstrek**

22. (1) **[Die Direkteur-generaal moet, na oorlegpleging met die raad,]** Die Hoof- Uitvoerende Beampte moet, op die wyse wat **[die Direkteur-generaal]** hy of sy die geskikste ag—

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

(i) die naam en nommer waaronder sodanige **[medisyne]** produk, mediese toestel of IVD geregistreer is en die voorwaardes (as daar is) waaraan dié **[medisyne]** produk, mediese toestel of IVD se registrasie onderworpe gestel is;

(ii) die terapeutiese doeltreffendheid en effek van sodanige **[medisyne]** produk;

(iii) die doel waarvoor, die omstandighede waaronder en die wyse waarop sodanige **[medisyne]** produk, mediese toestel of IVD gebruik behoort te word; en

(iv) enige ander aangeleentheid betreffende sodanige **[medisyne]** produk, mediese toestel of IVD wat, na die mening van die **[raad]** Hoof- Uitvoerende Beampte, vir hulle van waarde kan wees;

(b) so spoedig doenlik nadat die registrasie van 'n **[medisyne]** produk, mediese toestel of IVD, uitgesonderd 'n veterinêre medisyne, ingevolge artikel 16 ingetrek is, geneeshere, tandartse, aptekers, die breë publiek en die houer van die registrasiesertifikaat wat ten opsigte van daardie **[medisyne]** produk, mediese toestel of IVD uitgereik is, van die intrekking van sodanige registrasie laat verwittig.

(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.".

Wysiging van artikel 22A van Wet 101 van 1965, soos vervang deur artikel 13 van Wet 90 van 1997 en gewysig deur artikel 5 van Wet 59 van 2002

22. Artikel 22A van die Hoofwet word hierby gewysig—

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

greengazette

"(2) The Minister may, on the recommendation of the **[council]** Authority, prescribe the Scheduled substances referred to in this section.";

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

"*(b)* to any person apparently under the age of **[14]** 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C(1)*(a)*, 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]** 12 years";

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

"*(e)* in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of **[14]** 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C(1)*(a)*, 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]** 12 years";

(d) by the substitution in subsection (13) for paragraph *(a)* of the following paragraph:

"*(a)* to the applicant's furnishing the **[registrar]** Chief Executive Officer annually with the prescribed information;"; and

(e) by the substitution for subsection (15) of the following subsection:

"(15) Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the **[Interim Pharmacy Council of South Africa]** South African Pharmacy Council 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 shall be subject to such conditions as the Director-General may determine.".

Substitution of section 22B of Act 101 of 1965

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

"Publication of information relating to [medicine, Scheduled substance] products, medical devices or IVDs

22B. (1) Notwithstanding the provisions of section 34 the **[council]** Authority may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a **[medicine, Scheduled substance or medical device]** product, medical device or IVD.

(2) The Director-General may publish the information referred to in section (1) or release it to the public in a manner which he or she thinks fit.".

Amendment of section 22C of Act 101 of 1965

24. Section 22C of the principal Act is hereby amended—

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

"(1) Subject to the provisions of this section—

(a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner,

greengazette

"(2) Die Minister kan, op aanbeveling van die **[raad]** Owerheid, die gelyste stowwe in hierdie artikel bedoel, voorskryf.";

(b) deur paragraaf *(b)* van subartikel (4) deur die volgende paragraaf te vervang:

"*(b)* aan iemand wat oënskynlik jonger as **[14]** 12 jaar is, behalwe op 'n voorskrif uitgereik deur 'n gemagtigde voorskrywer en toeberei deur 'n apteker, apteker-intern of aptekersassistent of deur 'n veearts of 'n persoon wat die houer is van 'n lisensie in artikel 22C(1)*(a)* beoog, 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 ouer as **[14]** 12 jaar is;";

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

"*(e)* in die geval van 'n Bylae 2-stof, dit nie verkoop mag word nie aan iemand wat oënskynlik jonger as **[14]** 12 jaar is, behalwe op 'n voorskrif uitgereik deur 'n gemagtigde voorskrywer en toeberei deur 'n apteker, apteker-intern of aptekersassistent of deur 'n veearts of 'n persoon wat die houer is van 'n lisensie in artikel 22C(1)*(a)* beoog, 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 ouer as **[14]** 12 jaar is;";

(d) deur paragraaf *(a)* van subartikel (13) deur die volgende paragraaf te vervang:

"*(a)* daaraan dat die applikant jaarliks die voorgeskrewe inligting aan die **[registrateur]** Hoof- Uitvoerende Beampte verstrek;"; en

(e) deur subartikel (15) deur die volgende subartikel te vervang:

"(15) Ondanks andersluidende bepalings van hierdie artikel, kan die Direkteur-generaal na oorleg met die **[Interim Aptekersraad van Suid-Afrika]** Suid-Afrikaanse Aptekersraad soos bedoel in artikel 2 van die Wet op Aptekers, 1974 (Wet No. 53 van 1974), 'n permit aan 'n persoon of organisasie wat 'n gesondheidsdiens verrig, uitreik wat sodanige persoon of organisasie magtig om 'n bepaalde Bylae 1-, Bylae 2-, Bylae 3-, Bylae 4- of Bylae 5-stof te verkry, te besit, te gebruik of te voorsien, en sodanige permit is onderworpe aan die voorwaardes wat die Direkteur-generaal bepaal.".

Vervanging van artikel 22B van Wet 101 van 1965

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

"**Publikasie van inligting aangaande [medisyne, gelyste stof of mediese toestel] produkte, mediese toestelle of IVD's**

22B. (1) Ondanks die bepalings van artikel 34 kan die **[raad]** Owerheid, indien hy dit dienstig en in die openbare belang ag, inligting openbaar maak met betrekking tot die voorskryf, bereiding, toediening en gebruik van 'n **[medisyne, gelyste stof of mediese toestel]** produk, mediese toestel of IVD.

(2) Die Direkteur-generaal kan die inligting bedoel in subartikel (1) publiseer of dit aan die publiek beskikbaar stel op 'n wyse wat hy of sy goeddink.".

Wysiging van artikel 22C van Wet 101 van 1965

24. Artikel 22C van die Hoofwet word hierby gewysig—

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

"(1) Behoudens die bepalings van hierdie artikel—

(a) kan die Direkteur-generaal, op aansoek op die voorgeskrewe wyse en teen betaling van die voorgeskrewe gelde, 'n lisensie uitreik aan

greengazette

dentist, **[practitioner]** nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions;

(b) the **[council]** Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a **[medicine]** product, medical device or IVD a licence to manufacture, act as a wholesaler of or distribute, as the case may be, such **[medicine]** product, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the **[council]** Authority may determine.";

(b) by the substitution for subsection (2) of the following section:

"(2) A licence referred to in subsection (1)*(a)* shall not be issued unless the applicant has successfully completed a supplementary course determined by the South African Pharmacy Council after consultation with the Health Professions Council of South Africa**[, the Allied Health Professions Council of South Africa]** and the South African Nursing Council.";

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

"(3) The Director-General or the **[council]** Authority, as the case may be, 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 Director-General or the **[council]** Authority may deem necessary.";

(d) by the substitution in subsection (4) for the words preceding paragraph *(a)* of the following words:

"When the Director-General or the **[council]** Authority, as the case may be, grants or refuses an application for a licence—"; and

(e) by the substitution for subsection (6) of the following subsection:

"(6) No medical device or IVD establishment, manufacturer, wholesaler or distributer referred to in subsection (1)*(b)* shall manufacture, act as a wholesaler of or distribute, as the case may be, any **[medicine]** product, medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection.".

Substitution of section 22D of Act 101 of 1965

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

"**Period of validity and renewal of licence**

22D. A licence issued under section 22C shall be 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 Director-General or the **[council]** Authority, as the case may be, may allow and on payment of the prescribed fee.".

Amendment of section 22E of Act 101 of 1965

26. Section 22E of the principal Act is hereby amended—

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

"*(a)* has in or in connection with an application for a licence or renewal of a licence furnished the Director-General or the **[council]** Authority, as the case may be, with any information which to the knowledge of such holder is untrue or misleading in any material respect;";

(b) by the substitution in subsection (1) for the words following paragraph *(d)* of the following words:

"the Director-General or the **[council]** Authority, as the case may be, may by way of a notice in writing call upon him or her to show cause within the period specified in the notice, which period shall not be less

greengazette

'n geneesheer, tandarts, **[praktisyn,]** verpleegkundige of ander persoon wat kragtens die Wet op Gesondheidsberoepe, 1974, geregistreer is, om medisyne op te maak of toe te berei op die voorgeskrewe voorwaardes;

(b) kan die **[raad]** Owerheid, op aansoek op die voorgeskrewe wyse en teen betaling van die voorgeskrewe geld, 'n lisensie uitreik aan 'n mediese toestel- of IVD-inrigting, vervaardiger, groothandelaar of verspreider van 'n **[medisyne of mediese toestel]** produk, mediese toestel of IVD, om daardie **[medisyne of mediese toestel]** produk, mediese toestel of IVD te vervaardig, **[in te voer of uit te voer,]** op te tree as groothandelaar daarvan of dit te versprei, na gelang van die geval, op die voorwaardes betreffende die handhawing van die aanvaarbare gehalteversekeringsbeginsels en goeie vervaardigings- en verspreidingspraktyke wat die **[raad]** Owerheid bepaal.";

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

"(2) 'n Lisensie in subartikel (1)*(a)* bedoel, word nie uitgereik nie tensy die applikant 'n aanvullende kursus suksesvol voltooi het wat bepaal is deur die Suid-Afrikaanse Aptekersraad na oorlegpleging met die Raad vir Gesondheidsberoepe van Suid-Afrika**[, die Raad vir Verwante Gesondheidsberoepe van Suid-Afrika]** en die Suid-Afrikaanse Verpleegstersraad.";

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

"(3) Die Direkteur-generaal of die **[raad]** Owerheid, na gelang van die geval, kan van 'n applikant beoog in subartikel (1) vereis om benewens die inligting ingevolge genoemde subartikel deur die applikant verstrek, die inligting wat die Direkteur-generaal of die **[raad]** Owerheid nodig ag, te verstrek.";

(d) deur in subartikel (4) die woorde wat paragraaf *(a)* voorafgaan deur die volgende woorde te vervang:

"Wanneer die Direkteur-generaal of die **[raad]** Owerheid, na gelang van die geval, 'n aansoek om 'n lisensie toestaan of weier, moet—";

(e) deur subartikel (6) deur die volgende subartikel te vervang:

"(6) Geen mediese toestel- of IVD-inrigting, vervaardiger, groothandelaar of verspreider in subartikel (1)*(b)* bedoel, mag 'n **[medisyne]** produk, mediese toestel of IVD vervaardig, **[invoer, uitvoer,]** optree as groothandelaar daarvan of dit versprei nie, na gelang van die geval, tensy hy of sy die houer is van 'n lisensie in genoemde subartikel beoog.".

Vervanging van artikel 22D van Wet 101 van 1965

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

"**Geldigheidsduur en hernuwing van lisensie**

22D. 'n Lisensie kragtens artikel 22C uitgereik, is geldig vir die voorgeskrewe tydperk, maar kan hernieu word op aansoek op die voorgeskrewe wyse en voor die voorgeskrewe tydstip of die later tydstip wat die Direkteur-generaal of die **[raad]** Owerheid, na gelang van die geval, toelaat en teen betaling van die voorgeskrewe geld.".

Wysiging van artikel 22E van Wet 101 van 1965

26. Artikel 22E van die Hoofwet word hierby gewysig—

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

"*(a)* in of in verband met 'n aansoek om 'n lisensie of hernuwing van 'n lisensie enige inligting wat na die wete van so 'n houer in enige wesenlike opsig onwaar of misleidend is, aan die Direkteur-generaal of die **[raad]** Owerheid, na gelang van die geval, verstrek het;";

(b) deur in subartikel (1) die woorde wat op paragraaf *(d)* volg deur die volgende woorde te vervang:

"kan die Direkteur-generaal of die **[raad]** Owerheid, na gelang van die geval, hom of haar by wyse van 'n skriftelike kennisgewing aansê om binne die tydperk in die kennisgewing vermeld, wat nie minder as 20 dae

greengazette

than 20 days as from the date of the notice, why the licence in question should not be suspended or revoked."; and

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

"(2) The Director-General or the **[council]** Authority, as the case may be, may after considering the reasons furnished **[to him or her]** in terms of subsection (1)—

(a) suspend the licence in question for such period **[as he or she or the council]** the Director-General or the Authority may determine; or

(b) revoke the license in question.".

Amendment of section 22F of Act 101 of 1965, as amended by section 7 of Act 59 of 2002

27. Section 22F of the principal Act is hereby amended by the substitution in subsection (4) for paragraph *(c)* of the following paragraph:

"*(c)* where the product has been declared not substitutable by the **[council]** Authority.".

Amendment of section 22H of Act 101 of 1965

28. Section 22H of the principal Act is hereby amended by the substitution for subsections (1) and (2) of the following subsections, respectively:

"(1) *(a)* No wholesaler shall purchase **[medicines]** products from any source other than from the original manufacturer or from the primary importer of the finished product.

(b) A wholesaler shall sell **[medicines]** products only into the retail sector.

(c) Notwithstanding paragraphs *(a)* and *(b)*, a wholesaler may purchase from or sell to, other wholesalers or the public Schedule 0 substances.

(2) Subsection (1) shall not be construed as preventing the return of **[medicines]** products for credit purposes only, to the manufacturer or wholesaler from which that **[medicine]** product was initially obtained.".

Substitution of section 23 of Act 101 of 1965, as amended by section 22 of Act 65 of 1974

29. The following section is hereby substituted for section 23 of the principal Act:

"**Disposal of undesirable [medicines] products, medical devices or IVDs**

23. (1) If the **[council]** Authority is of the opinion that it is not in the public interest that any **[medicine]** product, medical device or IVD shall 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 **[medicine]** product, medical device or IVD which he or she has in his or her possession to the manufacturer thereof or (in the case of any imported **[medicine]** product, medical device or IVD) to the importer concerned or to deliver or send it to any other person designated by the **[council]** Authority.

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

(3) No person shall sell any **[medicine]** product, medical device or IVD which is the subject of a notice under subsection (1) which has not been set aside on appeal.".

greengazette

vanaf die datum van die kennisgewing mag wees nie, redes aan te voer waarom die betrokke lisensie nie opgeskort of ingetrek moet word nie."; en

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

"(2) Die Direkteur-generaal of die **[raad]** Owerheid, na gelang van die geval, kan na oorweging van die redes wat ingevolge subartikel (1) **[aan hom of haar]** verstrek is—

(a) die betrokke lisensie opskort vir die tydperk wat **[hy of sy of die raad]** die Direkteur-generaal of die Owerheid bepaal; of

(b) die betrokke lisensie intrek.".

Wysiging van artikel 22F van Wet 101 van 1965, soos gewysig deur artikel 7 van Wet 59 van 2002

27. Artikel 22F van die Hoofwet word hierby gewysig deur paragraaf *(c)* van subartikel (4) deur die volgende paragraaf te vervang:

"*(c)* waar die produk deur die **[raad]** Owerheid verklaar is nie vervangbaar te wees nie.".

Wysiging van artikel 22H van Wet 101 van 1965

28. Artikel 22H van die Hoofwet word hierby gewysig deur subartikels (1) en (2) deur onderskeidelik die volgende subartikels te vervang:

"(1) *(a)* 'n Groothandelaar mag nie **[medisyne]** produkte van enige ander bron as die oorspronklike vervaardiger of die primêre invoerder van die voltooide produk koop nie.

(b) 'n Groothandelaar mag **[medisyne]** produkte slegs in die kleinhandelsektor verkoop.

(c) Ondanks paragrawe *(a)* en *(b)* mag 'n groothandelaar Bylae 0-stowwe van en aan ander groothandelaars of die publiek koop en verkoop.

(2) Subartikel (1) word nie so uitgelê dat dit die teruggawe van **[medisyne]** produkte, slegs vir kredietdoeleindes, aan die vervaardiger of groothandelaar van wie dit aanvanklik verkry is, belet nie.".

Vervanging van artikel 23 van Wet 101 van 1965, soos gewysig deur artikel 22 van Wet 65 van 1974

29. Artikel 23 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Beskikking oor ongewenste [medisynes] produkte, mediese toestelle of IVD's**

23. (1) Indien die **[raad]** Owerheid van mening is dat dit nie in die openbare belang is dat 'n **[medisyne]** produk, mediese toestel of IVD aan die publiek beskikbaar moet wees nie, kan hy—

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

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

om enige hoeveelheid van sodanige **[medisyne]** produk, mediese toestel of IVD wat hy of sy in sy of haar besit het na die vervaardiger daarvan of (in die geval van 'n ingevoerde **[medisyne]** produk, mediese toestel of IVD) na die betrokke invoerder terug te stuur of om dit aan enige ander deur die **[raad]** Owerheid aangewese persoon te lewer of te stuur.

(2) Die **[raad]** Owerheid kan by skriftelike kennisgewing 'n mediese toestel- of IVD-inrigting, vervaardiger of invoerder van sodanige **[medisyne]** produk, mediese toestel of IVD wat enige hoeveelheid daarvan (met inbegrip van enige hoeveelheid ingevolge 'n lasgewing kragtens subartikel (1) aan hom of haar teruggestuur, gelewer of gestuur) in sy of haar besit het, of enige ander persoon aan wie 'n hoeveelheid van sodanige **[medisyne]** produk, mediese toestel of IVD aldus teruggestuur, gelewer of gestuur is, gelas om met daardie hoeveelheid te handel of daaroor te beskik op die wyse wat die **[raad]** Owerheid bepaal.

(3) Niemand mag enige **[medisyne]** produk, mediese toestel of IVD wat die onderwerp is van 'n kennisgewing ingevolge subartikel (1) wat nie op appèl tersyde gestel is nie, verkoop nie.".

greengazette

Substitution of section 24 of Act 101 of 1965, as substituted by section 15 of Act 90 of 1997 and amended by section 9 of Act 59 of 2002

30. The following section is hereby substituted for section 24 of the principal Act:

"**Appeal against decision of [council or] the Director-General**

24. (1) Any person aggrieved by the decision of the Director-General may within the prescribed period and in the prescribed manner make written representations with regard to such decision to the Minister.

(2) The Minister shall, after considering representations made in terms of subsection (1), confirm, set aside or vary the decision of the Director-General.".

Insertion of section 24A to Act 101 of 1965

31. The principal Act is hereby amended by the insertion after section 24 of the following section:

"**Appeal against decision of Authority**

24A. (1) Any person aggrieved by the decision of the Authority may appeal against such decision by notifying the Chief Executive Officer within 30 days of becoming aware of such decision of his or her intention to appeal and setting out the full grounds of appeal.

(2) Upon being notified the Chief Executive Officer shall meet with the appellant within 30 days of being so notified in the absence of legal representatives to try to resolve the matter, especially if the appeal involves administrative matters.

(3) Should the Chief Executive Officer and the appellant fail to resolve the matter as contemplated in subsection (2), the appellant shall within 30 days of being notified by the Chief Executive Officer of the failure to resolve the matter and upon payment of a prescribed fee, request the Minister in writing to convene an appeal committee.

(4) The appeal committee contemplated in subsection (3) shall—

(a) comprise the chairperson who shall have knowledge of the law and four other persons who shall have knowledge of the subject matter of appeal but with no financial or business interests in the affairs of the parties to the appeal, two of them nominated by the appellant and the other two by the Chief Executive Officer; and

(b) conduct the appeal hearing and make a decision within 30 days from the day when it first meets to hear the appeal.

(5) A party aggrieved by the decision of the appeal committee may approach the High Court for a judicial review.".

Substitution of section 25 of Act 101 of 1965, as substituted by section 10 of Act 59 of 2002

32. The following section is hereby substituted for section 25 of the principal Act:

"**Privileges of [council] Authority and committees**

25. The Authority, persons contracted by the Authority to perform work for the Authority, committees appointed in terms of this Act or their members are not liable in respect of anything done in good faith under this Act.".

greengazette

Vervanging van artikel 24 van Wet 101 van 1965, soos vervang deur artikel 15 van Wet 90 van 1997 en gewysig deur artikel 9 van Wet 59 van 2002

30. Artikel 24 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Appèl teen beslissing van [raad of] Direkteur-generaal**

24. (1) 'n Persoon wat hom of haar veronreg ag deur 'n beslissing van die Direkteur-generaal, kan binne die voorgeskrewe tydperk en op die voorgeskrewe wyse skriftelike vertoë met betrekking tot sodanige besluit tot die Minister rig.

(2) Die Minister moet, na oorweging van vertoë wat ingevolge subartikel (1) gerig is, die besluit van die Direkteur-generaal bevestig, tersyde stel of verander.".

Invoeging van artikel 24A in Wet 101 van 1965

31. Die Hoofwet word hierby gewysig deur die volgende artikel na artikel 24 in te voeg:

"**Appèl teen besluit van Owerheid**

24A. (1) 'n Persoon wat hom of haar veronreg ag deur die besluit van die Owerheid, kan teen sodanige besluit appelleer deur die Hoof- Uitvoerende Beampte binne 30 dae nadat hy of sy van sodanige besluit bewus geraak het, in kennis te stel van sy of haar voorneme om te appelleer, met 'n uiteensetting van die volle gronde van appèl.

(2) Na ontvangs van sodanige kennisgewing moet die Hoof- Uitvoerende Beampte binne 30 dae na sodanige kennisgewing met die appellant vergader in afwesigheid van regsverteenwoordigers om te probeer om die aangeleentheid op te los, veral as die appèl oor administratiewe aangeleenthede gaan.

(3) Indien die Hoof- Uitvoerende Beampte en die appellant nie daarin slaag om die aangeleentheid op te los nie soos in subartikel (2) beoog, moet die appellant binne 30 dae na kennisgewing deur die Hoof- Uitvoerende Beampte van die mislukking om die aangeleentheid op te los, en met betaling van die voorgeskrewe gelde, die Minister skriftelik versoek om 'n appèlkomitee byeen te roep.

(4) Die appèlkomitee in subartikel (3) beoog, moet—

(a) bestaan uit die voorsitter, wat kennis van die reg moet hê, en vier ander persone wat kennis van die onderwerp van die appèl moet hê maar geen finansiële of sakebelange by die sake van die partye by die appèl nie, en twee van hulle moet deur die appellant benoem word en die ander twee deur die Hoof- Uitvoerende Beampte; en

(b) die appèlverhoor waarneem en 'n besluit neem binne 30 dae na die dag waarop hy die eerste keer byeenkom om die appèl aan te hoor.

(5) 'n Party wat hom veronreg ag deur die besluit van die appèlkomitee, kan die Hoë Hof nader vir 'n geregtelike hersiening.".

Vervanging van artikel 25 van Wet 101 van 1965, soos vervang deur artikel 10 van Wet 59 van 2002

32. Artikel 25 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Privilegie van [raad] Owerheid en komitees**

25. Die Owerheid, persone wat deur die Owerheid gekontrakteer is om werk vir die Owerheid te verrig, komitees wat ingevolge hierdie Wet aangestel is of hulle lede is nie aanspreeklik ten opsigte van enigiets wat te goeder trou kragtens hierdie Wet gedoen is nie.".

greengazette

Substitution of section 26 of Act 101 of 1965, as substituted by section 24 of Act 65 of 1974, section 1 of Act 19 of 1976 and section 10 of Act 17 of 1979

33. The following section is hereby substituted for section 26 of the principal Act:

"**Inspectors**

26. (1) The **[Director-General]** Chief Executive Officer may authorize such persons as inspectors**[,]** as he or she may consider necessary for the proper enforcement of this Act.

(2) Every inspector shall be furnished with a certificate signed by the **[Director-General]** Chief Executive Officer and stating that he or she has been authorized as an inspector under this Act.

(3) An inspector shall, before he or she exercises or performs any power or function under this Act, produce and exhibit to any person affected **[hereby]** by such exercise or performance, the certificate referred to in subsection (2).".

Substitution of section 27 of Act 101 of 1965, as substituted by section 11 of Act 17 of 1979

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

"**Analysts, pharmacologists, engineers, technicians and pathologists**

27. [The Director-General] Chief Executive Officer may grant such authority to such analysts, pharmacologists, engineers, technicians and pathologists or any other appropriately qualified person as he or she may consider necessary for the proper enforcement of this Act.".

Amendment of section 28 of Act 101 of 1965

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

(a) by the substitution in subsection (1)*(a)* for subparagraph (i) of the following subparagraph:

"(i) any place or premises from which a person, authorized under this Act to compound and dispense medicines or Scheduled substances, handles products, medical devices or IVDs or from which the holder of a licence as contemplated in section 22C(1)*(b)* conducts a business; or";

(b) by the substitution in subsection (1) for paragraphs *(b)* and *(c)* of the following paragraphs, respectively:

"*(b)* inspect any product, medical device or IVD, or any book, record or document found in or upon the premises, place, vehicle, vessel or aircraft contemplated in subparagraph (ii) of subsection (1)*(a)*;

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

(c) by the addition in subsection (1) of the following paragraph:

"*(d)* take so many samples of any such product, medical device or IVD as he or she may consider necessary for the purpose of testing, examination or analysis in terms of the provisions of this Act."; and

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

"(2) *(a)* Any sample taken in terms of paragraph *(d)* of subsection (1) shall—

(i) 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,]** product, medical device or IVD, or if there is no such person or if he or she is absent for any reason, in the presence of any other witness**[, shall];**

(ii) forthwith be packed and sealed and suitably labelled or marked in such manner as its nature may permit **[and shall]**; and

greengazette

Vervanging van artikel 26 van Wet 101 van 1965, soos vervang deur artikel 24 van Wet 65 van 1974, artikel 1 van Wet 19 van 1976 en artikel 10 van Wet 17 van 1979

33. Artikel 26 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Inspekteurs**

26. (1) Die **[Direkteur-generaal]** Hoof- Uitvoerende Beampte kan die persone as inspekteurs magtig wat hy of sy vir die behoorlike uitvoering van hierdie Wet nodig ag.

(2) Elke inspekteur moet van 'n deur die **[Direkteur-generaal]** Hoof- Uitvoerende Beampte ondertekende sertifikaat voorsien word waarin verklaar word dat hy of sy kragtens hierdie Wet as 'n inspekteur gemagtig is.

(3) Voordat 'n inspekteur enige bevoegdheid of werksaamheid kragtens hierdie Wet uitoefen of verrig, moet hy of sy aan enigiemand wat **[daardeur]** deur sodanige uitoefening of verrigting geraak word, die in subartikel (2) bedoelde sertifikaat voorlê en vertoon.".

Vervanging van artikel 27 van Wet 101 van 1965, soos vervang deur artikel 11 van Wet 17 van 1979

34. Artikel 27 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Ontleders, farmakoloë, ingenieurs, tegnici en patoloë**

27. Die **[Direkteur-generaal]** Hoof- Uitvoerende Beampte kan die magtiging aan die ontleders, farmakoloë, ingenieurs, tegnici en patoloë of enige ander gepas gekwalifiseerde persoon verleen wat hy of sy vir die behoorlike uitvoering van hierdie Wet nodig ag.".

Wysiging van artikel 28 van Wet 101 van 1965

35. Artikel 28 van die Hoofwet word hierby gewysig—

(a) deur subparagraaf (i) van subartikel (1)*(a)* deur die volgende subparagraaf te vervang:

"(i) 'n plek of perseel vanwaar 'n persoon wat ingevolge hierdie Wet gemagtig is om medisyne of gelyste stowwe op te maak en te resepteer, produkte, mediese toestelle of IVD's hanteer of van waar die houer van 'n lisensie soos beoog in artikel 22C(1)*(b)* 'n besigheid bedryf; of";

(b) deur paragrawe *(b)* en *(c)* van subartikel (1) deur onderskeidelik die volgende paragrawe te vervang:

"*(b)* enige produk, mediese toestel of IVD, of enige boek, aantekening of dokumente wat aangetref word in of op die perseel, plek, voertuig, vaartuig of lugvaartuig in subparagraaf (ii) van subartikel (1)*(a)* beoog, inspekteer;

(c) beslag lê op 'n produk, mediese toestel of IVD, enige boek, aantekening of dokumente wat in of op sodanige perseel, plek, voertuig, vaartuig of lugvaartuig aangetref word en skynbaar bewys kan lewer van 'n oortreding van 'n bepaling van hierdie Wet;";

(c) deur die volgende paragraaf in subartikel (1) by te voeg:

"*(d)* soveel monsters neem van enige sodanige produk, mediese toestel of IVD wat hy of sy nodig ag vir die doel van toetsing, ondersoek of ontleding ingevolge die bepalings van hierdie Wet.";

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

"(2) *(a)* 'n Monster wat ingevolge paragraaf *(d)* van subartikel (1) geneem word, moet—

(i) ooreenkomstig die voorgeskrewe metodes en in die teenwoordigheid van die persoon wat toesig het oor die **[medisyne of gelyste stof]** produk, mediese toestel of IVD geneem word, of, as daar nie so 'n persoon is nie of as hy of sy om die een of ander rede afwesig is, in die teenwoordigheid van 'n ander getuie;

(ii) **[word]** dadelik op die wyse wat die aard daarvan toelaat, verpak en verseël en behoorlik geëtiketteer of gemerk word; en

greengazette

(iii) then be transmitted to an analyst, pharmacologist, technician or pathologist together with a certificate in the prescribed **[forms]** form signed by such inspector**[and a]**.

(b) 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]** product, medical device or IVD or his or her agent."; and

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

"(4) The owner of the **[medicine or Scheduled substance]** product, medical device or IVD from which the sample was taken may claim from the **[Director-General]** the Authority an amount equal to the market value thereof.".

Amendment of section 29 of Act 101 of 1965, as amended by section 27 of Act 65 of 1974, section 12 of Act 94 of 1991 and section 17 of Act 90 of 1997

36. Section 29 of the principal Act is hereby amended—

(a) by the substitution for paragraph *(e)* of the following paragraph:

"*(e)* contravenes or fails to comply with any condition imposed under section **[15(7)]** 15(6)";

(b) by the substitution in paragraph *(h)* for the words preceding subparagraph (i) of the following words:

"makes any false or misleading statement in connection with any **[medicine or Scheduled substance]** product, medical device or IVD—"; and

(c) by the substitution for paragraph *(i)* of the following paragraph:

"*(i)* sells any **[medicine or Scheduled substance]** product upon the container of which a false or misleading statement in connection with the contents is written; or".

Amendment of section 30 of Act 101 of 1965, as amended by section 28 of Act 65 of 1974, section 13 of Act 94 of 1991 and section 18 of Act 90 of 1997

37. Section 30 of the principal Act is hereby amended—

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

"(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any **[medicine or Scheduled substance]** product, medical device or IVD in respect of which the offence has been committed to be forfeited to the State."; and

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

"(3) Any **[medicine or Scheduled substance]** product, medical device or IVD forfeited under this Act shall be destroyed or otherwise dealt with as the **[Director-General]** Chief Executive Officer may direct.".

Amendment of section 31 of Act 101 of 1965, as amended by section 29 of Act 65 of 1974, section 13 of Act 17 of 1979 and section 19 of Act 90 of 1997

38. Section 31 of the principal Act is hereby amended—

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

"*(a)* any quantity of a **[medicine or Scheduled substance]** product, medical device or IVD in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample;"; and

(b) by the substitution for paragraph *(d)* of the following paragraph:

"*(d)* any statement or entry contained in any book, record or document kept by any owner of a **[medicine product or Scheduled substance,]** product, medical device or IVD or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, such owner, shall be admissible in evidence against him or her as an admission of the facts set forth in that statement or entry, unless **[it is proved]**

greengazette

(iii) **[word]** dan gestuur word aan 'n ontleder, farmakoloog, tegnikus of patoloog tesame met 'n sertifikaat in die voorgeskrewe vorm wat deur die inspekteur onderteken is **[en 'n]**.

(b) 'n Afskrif van voormelde sertifikaat word aan die eienaar of verkoper van sodanige **[medisyne of gelyste stof]** produk, mediese toestel of IVD of sy agent oorhandig of per aangetekende pos gestuur."; en

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

"(4) Die eienaar van die **[medisyne of gelyste stof]** produk, mediese toestel of IVD waarvan die monster geneem is, kan 'n bedrag gelykstaande met die markwaarde daarvan van die **[Direkteur-generaal]** Owerheid eis.".

Wysiging van artikel 29 van Wet 101 van 1965, soos gewysig deur artikel 27 van Wet 65 van 1974, artikel 12 van Wet 94 van 1991 en artikel 17 van Wet 90 van 1997

36. Artikel 29 van die Hoofwet word hierby gewysig—

(a) deur paragraaf *(e)* deur die volgende paragraaf te vervang:

"*(e)* 'n voorwaarde opgelê kragtens artikel **[15(7)]** 15(6) oortree of versuim om daaraan te voldoen; of";

(b) deur in paragraaf *(h)* die woorde wat subparagraaf (i) voorafgaan deur die volgende woorde vervang:

"in verband met 'n **[medisyne of gelyste stof]** produk, mediese toestel of IVD 'n valse of misleidende verklaring maak—"; en

(c) deur paragraaf *(i)* deur die volgende paragraaf te vervang:

"*(i)* 'n **[medisyne of gelyste stof]** produk, op die houer waarvan 'n valse of misleidende verklaring in verband met die inhoud geskryf is, verkoop; of".

Wysiging van artikel 30 van Wet 101 van 1965, soos gewysig deur artikel 28 van Wet 65 van 1974, artikel 13 van Wet 94 van 1991 en artikel 18 van Wet 90 van 1997

37. Artikel 30 van die Hoofwet word hierby gewysig—

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

"(2) Die hof wat iemand aan 'n misdryf ingevolge hierdie Wet skuldig bevind, kan op versoek van die vervolger, enige **[medisyne of gelyste stof]** produk, mediese toestel of IVD ten opsigte waarvan die misdryf gepleeg is, aan die Staat verbeurd verklaar."; en

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

"(3) 'n Kragtens hierdie Wet verbeurdverklaarde **[medisyne of gelyste stof]** produk, mediese toestel of IVD word vernietig of andersins mee gehandel soos die **[Direkteur-generaal]** Hoof- Uitvoerende Beampte gelas.".

Wysiging van artikel 31 van Wet 101 van 1965, soos gewysig deur artikel 29 van Wet 65 van 1974, artikel 13 van Wet 17 van 1979 en artikel 19 van Wet 90 van 1997

38. Artikel 31 van die Hoofwet word hierby gewysig—

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

"*(a)* word 'n hoeveelheid **[medisyne of gelyste stof]** produkte, mediese toestelle of IVD's wat in of op 'n perseel, plek, voertuig, vaartuig of **[vliegtuig]** lugvaartuig is wanneer 'n monster daarvan ooreenkomstig die bepalings van hierdie Wet geneem word, tensy die teendeel bewys word, geag dieselfde eienskappe te besit as daardie monster;" en

(b) deur paragraaf *(d)* deur die volgende paragraaf te vervang:

"*(d)* is 'n verklaring of inskrywing vervat in 'n boek, aantekening of dokument wat deur 'n eienaar van 'n **[medisyne of gelyste stof]** produk, mediese toestel of IVD of deur die bestuurder, agent of werknemer van sodanige eienaar gehou word, of wat gevind word op of in 'n perseel wat deur sodanige eienaar geokkupeer word, of op 'n voertuig wat in die besigheid van sodanige eienaar gebruik

greengazette

evidence to the contrary which raises a reasonable doubt shows that that statement or entry was not made by such owner, or by any manager, agent or employee of such owner in the course of his or her work as manager, or in the course of his or her agency or employment.".

Substitution of section 33A of Act 101 of 1965

39. The following section is hereby substituted for section 33A of the principal Act:

"**Funds of [council] Authority**

33A. (1) The funds of the **[council]** Authority shall consist of—

(a) State funds received through the Department of Health;

(b) fees raised and interest on overdue fees;

(c) money accruing to the **[council]** Authority from any other source.

(2) *(a)* The **[council]** Authority may accept money or other goods donated or bequeathed to the **[council]** Authority, provided no condition is attached to such donation or bequest.

(b) Details of any such donation or bequest shall be specified in the relevant annual report of the **[council]** Authority.

(3) The **[council]** Authority shall utilise its funds for the defrayal of expenses incurred by the **[council]** Authority in the performance of its functions under this Act.

(4) The **[council]** Authority shall open an account with a bank as defined in section 1(1) of the Banks Act, 1990 (Act No. 94 of 1990), and shall deposit in that account all money referred to in subsections (1) and (2).

(5) The **[council]** Authority shall keep full and proper records of all money received or expended, of its assets and liabilities and of its financial transactions.

(6) The records and annual financial statements referred to in subsection (5) shall be audited by the Auditor-General.

(7) The **[council]** Authority may invest money which is deposited in terms of subsection (4) and which is not required for immediate use in any manner as it may deem fit.

(8) Any money which at the close of the **[council's]** Authority's financial year stands to the credit of the **[council]** Authority in the account referred to in subsection (4) and money which has been invested in terms of subsection (7), shall be carried forward to the next financial year as a credit in the account of the **[council]** Authority.".

Amendment of section 34A of Act 101 of 1965, as substituted by section 15 of Act 94 of 1991 and section 22 of Act 90 of 1997

40. Section 34A of the principal Act is hereby amended by the addition of the following subsection:

"(3) The Chief Executive Officer may, in writing, authorise any staff member of the Authority to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function conferred or imposed on the Chief Executive Officer in terms of this Act.".

Amendment of section 35 of Act 101 of 1965, as substituted by section 23 of Act 90 of 1997 and amended by section 12 of Act 59 of 2002

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

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

"The Minister may, in consultation with the **[council]** Authority, make regulations—";

greengazette

word, toelaatbaar by wyse van getuienis teen hom of haar as 'n erkenning van die feite uiteengesit in daardie verklaring of inskrywing, tensy **[bewys word]** bewys tot die teendeel wat redelike twyfel veroorsaak, toon dat daardie verklaring of inskrywing nie deur sodanige eienaar of deur 'n bestuurder, agent of werknemer van sodanige eienaar in die loop van sy of haar werk as bestuurder of in die loop van sy of haar agentskap of diens gemaak is nie.".

Vervanging van artikel 33A van Wet 101 van 1965

39. Artikel 33A van die Hoofwet word hierby deur die volgende artikel vervang:

"**Fondse van [raad] Owerheid**

33A. (1) Die fondse van die **[raad]** Owerheid bestaan uit—

(a) Staatsfondse ontvang deur die Departement van Gesondheid;

(b) geld wat geïn word, en rente op agterstallige gelde;

(c) geld wat die **[raad]** Owerheid uit 'n ander bron toeval.

(2) *(a)* Die **[raad]** Owerheid kan geld of ander goed wat aan die **[raad]** Owerheid geskenk of bemaak is, aanvaar, mits geen voorwaarde aan sodanige skenking of bemaking verbonde is nie.

(b) Besonderhede van enige sodanige skenking of bemaking moet in die betrokke jaarverslag van die **[raad]** Owerheid vermeld word.

(3) Die **[raad]** Owerheid wend sy fondse aan ter bestryding van uitgawes wat die **[raad]** Owerheid by die verrigting van sy werksaamhede kragtens hierdie Wet aangaan.

(4) Die **[raad]** Owerheid moet 'n rekening open by 'n bank soos omskryf in artikel 1(1) van die Bankwet, 1990 (Wet No. 94 van 1990), en moet in daardie rekening alle geld bedoel in subartikels (1) en (2) stort.

(5) Die **[raad]** Owerheid moet volledige en juiste aantekeninge hou van alle geld wat hy ontvang of bestee, van sy bates en laste en sy finansiële transaksies.

(6) Die aantekeninge en finansiële jaarstate in subartikel (5) bedoel, moet deur die Ouditeur-generaal geouditeer word.

(7) Die **[raad]** Owerheid kan geld wat ingevolge subartikel (4) gestort is en nie vir onmiddellike gebruik nodig is nie, belê op 'n wyse wat hy goeddink.

(8) Geld wat by die sluiting van die **[raad]** Owerheid se boekjaar tot krediet van die **[raad]** Owerheid staan in die rekening bedoel in subartikel (4), asook geld wat ingevolge subartikel (7) belê is, word as 'n krediet in die rekening van die **[raad]** Owerheid na die daaropvolgende boekjaar oorgedra.".

Wysiging van artikel 34A van Wet 101 van 1965, soos vervang deur artikel 15 van Wet 94 van 1991 en artikel 22 van Wet 90 van 1997

40. Artikel 34A van die Hoofwet word hierby gewysig deur die volgende subartikel by te voeg:

"(3) Die Hoof- Uitvoerende Beampte kan enige personeellid van die Owerheid skriftelik magtig om in die algemeen of in 'n bepaalde geval of in gevalle van 'n bepaalde aard enige bevoegdheid, plig of werksaamheid uit te oefen of te verrig wat ingevolge hierdie Wet aan die Hoof- Uitvoerende Beampte verleen of toegewys is.".

Wysiging van artikel 35 van Wet 101 van 1965, soos vervang deur artikel 23 van Wet 90 van 1997 en gewysig deur artikel 12 van Wet 59 van 2002

41. Artikel 35 van die Hoofwet word hierby gewysig—

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

"(1) Die Minister kan, in oorleg met die **[raad]** Owerheid, regulasies uitvaardig—";

greengazette

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

(xii) prescribing the particulars which shall be published in the *Gazette* in respect of any application for registration referred to in section **[15(11)]** 15(10);";

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

"(xiii) relating to the responsibilities of both medical device and IVD establishments and users of medical devices and IVDs, in relation to the use, training, maintenance, calibration, post-marketing surveillance, sterilization, disinfection, recall, decomposition, decommissioning or decontamination of medical devices and IVDs;";

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

"(xxxi) prescribing the fee to be paid to the **[registrar]** Authority in respect of an application for the registration, and in respect of the registration of a **[medicine, Scheduled substance or medical device]** product, medical device or IVD, the fee to be paid annually to the **[registrar]** Authority in respect of the retention of the certification or the registration of a **[medicine, Scheduled substance or medical device]** product, medical device or IVD and the date on which such annual fee shall be paid;";

(e) by the substitution in subsection (1) for paragraph (xxxiii) of the following paragraph:

"(xxxiii) relating to appeals against decisions of the Director-General or the **[council]** Authority;";

(f) by the substitution in subsection (1) for paragraph (xxxvii) of the following paragraph:

"(xxxvii) relating to the scientific, pharmaceutical, clinical, technical and other skills required by members of staff of the Authority to evaluate the quality, efficacy and safety of products, medical devices and IVDs;";

(g) by the insertion after paragraph (xxxix) of the following paragraphs, the existing paragraphs (xl) and (xli) becoming paragraphs (xliv) and (xlv), respectively:

"(xl) relating to products, medical devices or IVDs in respect of matters contemplated in paragraphs (i) up to and including paragraph (xi) and paragraphs (xxiii), (xxiv), (xxxii), (xxxiv) and (xxxviii);

(xli) relating to the control of products, medical devices and IVD in general;

(xlii) relating to the licensing for possessing or using certain products, medical devices or IVDs;

(xliii) relating to time frames for the consideration of applications by the Authority;";

(h) by the substitution in subsection (3) for paragraph *(b)* of the following paragraph:

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

(i) by the substitution for subsection (5) of the following subsection:

"(5) Regulations made under subsection (1)(xi) may prescribe that any **[medicine]** product, medical device or IVD or any component thereof shall comply with the requirements set out in any publication which in the opinion of the **[council]** Authority is generally recognised as authoritative.";

(j) by the substitution for subsection (6) of the following subsection:

"(6) Regulations may be made under this section in respect of particular products, medical devices or IVDs or classes or categories in respect thereof other than particular classes or categories of products, medical devices or IVDs, and different regulations may be so made in respect of different products, medical devices or IVDs or different classes or categories of products, medical devices or IVDs."; and

greengazette

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

"(xii) wat die besonderhede voorskryf wat in die *Staatskoerant* afgekondig moet word ten opsigte van 'n aansoek om registrasie in artikel **[15(11)]** 15(10) bedoel;";

(c) deur paragraaf (xiii) van subartikel (1) deur die volgende paragraaf te vervang:

"(xiii) betreffende die verantwoordelikhede van sowel mediese toestel- en IVD-inrigtings as gebruikers van mediese toestelle en IVD's met betrekking tot die gebruik, opleiding, instandhouding, kalibrering, monitering na bemarking, sterilisering, disinfektering, terugroeping, ontbinding, uitdiensstelling of ontsmetting van mediese toestelle en IVD's;";

(d) deur paragraaf (xxxi) van subartikel (1) deur die volgende paragraaf te vervang:

"(xxxi) wat die geld wat aan die **[registrateur]** Owerheid betaal moet word ten opsigte van 'n aansoek om registrasie, en ten opsigte van die registrasie, van 'n **[medisyne, gelyste stof of mediese toestel]** produk, mediese toestel of IVD, die geld wat jaarliks aan die **[registrateur]** Owerheid betaal moet word ten opsigte van die behoud van die registrasie van 'n **[medisyne, gelyste stof of mediese toestel]** produk, mediese toestel of IVD en die datum waarop sodanige jaarlikse geld betaal moet word, voorskryf;";

(e) deur paragraaf (xxxiii) van subartikel (1) deur die volgende paragraaf te vervang:

"(xxxiii) betreffende appèlle teen beslissings van die Direkteur-generaal of die **[raad]** Owerheid;";

(f) deur paragraaf (xxxvii) van subartikel (1) deur die volgende paragraaf te vervang:

"(xxxvii) betreffende die wetenskaplike, farmaseutiese, kliniese, tegniese en ander kundigheid wat vereis word van 'n lid van die personeel van die **[raad]** Owerheid **[of van 'n lid van die uitvoerende komitee van die raad]** om die veiligheid, gehalte en doeltreffendheid van **[medisyne]** produkte, mediese toestelle en IVD's te evalueer;";

(g) deur die volgende paragrawe na paragraaf (xxxix) in te voeg, terwyl die bestaande paragrawe (xl) en (xli) onderskeidelik paragrawe (xliv) en (xlv) word:

"(xl) betreffende produkte, mediese toestelle of IVD's ten opsigte van aangeleenthede beoog in paragraaf (i) tot en met paragraaf (xi) en paragrawe (xxiii), (xxiv), (xxxii), (xxxiv) en (xxxviii);

(xli) betreffende die beheer oor produkte, mediese toestelle en IVD's oor die algemeen;

(xlii) betreffende die lisensiëring vir die besit of gebruik van sekere produkte, mediese toestelle of IVD's;

(xlii) betreffende tydraamwerke vir die oorweging van aansoeke deur die Owerheid;";

(h) deur paragraaf *(b)* van subartikel (3) deur die volgende paragraaf te vervang:

"*(b)* enige regulasie ten opsigte waarvan die Minister, na oorleg met die **[raad]** Owerheid, van oordeel is dat die uitvaardiging daarvan sonder versuim in die openbare belang nodig is.";

(i) deur subartikel (5) deur die volgende subartikel te vervang:

"(5) Regulasies wat kragtens subartikel (1)(xi) uitgevaardig word, kan voorskryf dat 'n **[medisyne]** produk, mediese toestel of IVD of bestanddeel daarvan moet voldoen aan die vereistes wat uiteengesit word in 'n publikasie wat na die mening van die **[raad]** Owerheid algemeen as gesaghebbend erken word.";

(j) deur subartikel (6) deur die volgende subartikel te vervang:

"(6) Regulasies kan kragtens hierdie artikel uitgevaardig word ten opsigte van bepaalde produkte, mediese toestelle of IVD's of klasse of kategorieë ten opsigte daarvan uitgesonderd bepaalde klasse of kategorieë produkte, mediese toestelle of IVD's, en verskillende regulasies kan aldus ten opsigte van verskillende produkte, mediese toestelle of IVD's of verskillende klasse of kategorieë produkte, mediese toestelle of IVD's uitgevaardig word."; en

greengazette

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

"(8) Notwithstanding the provisions of subsection (1), the Minister may, if he or she deems it to be in the public interest, after consultation with the **[executive committee appointed under section 9,]** Authority, make regulations relating to any matter referred to in subsection (1) or amend or repeal any regulation made in terms of that subsection.".

Substitution of section 36 of Act 101 of 1965, as amended by section 32 of Act 65 of 1974

42. The following section is hereby substituted for section 36 of the principal Act:

"**Exclusion of any product, medical device or IVD from operation of Act**

36. (1) The Minister may, on the recommendation of the Authority, by notice in the *Gazette* exclude, subject to such conditions as he or she may determine, any product, medical device or IVD from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice.

(2) Notwithstanding subsection (1), the exclusion of any product from the operation of section 22G shall be on the recommendation of the Pricing Committee.".

Substitution of section 37A of Act 101 of 1965, as substituted by section 25 of Act 90 of 1997

43. The following section is hereby substituted for section 37A of the principal Act:

"**Amendment of Schedules**

37A. Notwithstanding the provisions of section 35(2), the Minister may, on the recommendation of the **[council]** Authority, from time to time by notice in the *Gazette* amend any Schedule prescribed under section 22A(2) by the inclusion therein or the deletion therefrom of any medicine or other substance, or in any other manner.".

Transitional measures

44. (1) Medicines and medical devices that are registered at the date of commencement of this Act shall be deemed to be registered in terms of the principal Act, and the Chief Executive Officer shall enter them in the relevant register.

(2) The Medicines Control Council shall cease to exist the day before this Act is brought into operation.

(3) Anything done by the Council which could have been done by the Authority in terms of this Act shall be deemed to have been done by the Authority.

Short title and commencement

45. This Act is called the Medicines and Related Substances Amendment Act, 2008, and comes into operation on a date fixed by the President by proclamation in the *Gazette*.

greengazette

(k) deur subartikel (8) deur die volgende subartikel te vervang:

"(8) Ondanks die bepalings van subartikel (1) kan die Minister, indien hy of sy dit in die openbare belang ag, na oorleg met die **[uitvoerende komitee kragtens artikel 9 aangestel,]** Owerheid, regulasies uitvaardig betreffende enige aangeleentheid bedoel in subartikel (1) of enige regulasie uitgevaardig ingevolge daardie subartikel, wysig of herroep.".

Vervanging van artikel 36 van Wet 101 van 1965, soos gewysig deur artikel 32 van Wet 65 van 1974

42. Artikel 36 van die Hoofwet word hierby deur die volgende artikel vervang:

"**Uitsluiting van enige produk, mediese toestel of IVD van toepassing van Wet**

36. (1) Die Minister kan, op aanbeveling van die Owerheid, by kennisgewing in die *Staatskoerant* enige produk, mediese toestel of IVD, onderworpe aan die voorwaardes wat hy of sy bepaal, uitsluit van die toepassing van enige van of al die bepalings van hierdie Wet en kan so 'n kennisgewing insgelyks wysig of intrek.

(2) Ondanks subartikel (1) geskied die uitsluiting van enige produk van die toepassing van artikel 22G op aanbeveling van die Pryskomitee.".

Vervanging van artikel 37A van Wet 101 van 1965, soos gewysig deur artikel 25 van Wet 90 van 1997

43. Artikel 37A van die Hoofwet word hierby deur die volgende artikel vervang:

"**Wysiging van Bylaes**

37A. Ondanks die bepalings van artikel 35(2) kan die Minister op aanbeveling van die **[raad]** Owerheid enige Bylae kragtens artikel 22A(2) voorgeskryf van tyd tot tyd by kennisgewing in die *Staatskoerant* wysig deur 'n medisyne of ander stof daarby in te sluit of daaruit te skrap, of op enige ander wyse.".

Oorgangsmaatreëls

44. (1) Medisyne en mediese toestelle wat geregistreer is op die datum van inwerkingtreding van hierdie Wet, word geag ingevolge die Hoofwet geregistreer te wees, en die Hoof- Uitvoerende Beampte moet dit in die betrokke register aanteken.

(2) Die Medisynebeheerraad hou op bestaan op die dag voordat hierdie Wet in werking tree.

(3) Enigiets wat deur die Raad gedoen is wat deur die Owerheid gedoen sou word ingevolge hierdie Wet, word geag deur die Owerheid gedoen te wees.

Kort titel en inwerkingtreding

45. Hierdie Wet heet die Wysigingswet op Medisyne en Verwante Stowwe, 2008, en tree in werking op 'n datum wat die President by proklamasie in die *Staatskoerant* bepaal.

greengazette