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REPUBLIEK VAN SUID-AFRIKA

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THE PRESIDENCY

No. 19 8 January 2016

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

Act No. 14 of 2015: Medicines and Related Substances Amendment Act, 2015

DIE PRESIDENSIE

No. 19 8 Januarie 2016

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

Wet No 14 van 2015: Wysigingswet op Medisyne en Verwante Stowwe, 2015

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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

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 24 December 2015)

ACT

To amend the Medicines and Related Substances Act, 1965, so as to define certain expressions and to delete or amend certain definitions; to provide for the objects and functions of the Authority; to provide for the composition, appointment of chairperson, vice-chairperson and members, disqualification of members, meetings and committees of the Board of the Authority; to require the Minister to consult with the Pricing Committee when prescribing acceptable and prohibited acts in relation to bonusing; to replace the word "products" with the word "medicines" and expression "Scheduled substances" in order to correctly reflect the subject matter of the said Act; and to effect certain technical corrections; and to provide 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 substituted by section 1 of Act 65 of 1974 and amended by section 1 of Act 17 of 1979, section 1 of Act 20 of 1981, section 1 of Act 94 of 1991, section 1 of Act 49 of 1996, section 1 of Act 90 of 1997, section 1 of Act 59 of 2002 and section 1 of Act 72 of 2008

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 **[product]** medicine, Scheduled substance, 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, electronic media (including radio and television) 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 **[product]** medicine, Scheduled substance, medical device or IVD, and **'advertise'** has a corresponding meaning;'';

(b) by the deletion of the definition of ''advisory committee'';

ALGEMENE VERDUIDELIKENDE NOTA:

[ ] Woorde in vet druk in vierkantige hakies dui weglatings uit bestaande wetgewing aan.

________ Woorde onderstreep met 'n vol streep dui invoegings in bestaande wetgewing aan.

(Engelse teks deur die President geteken)
(Goedgekeur op 24 Desember 2015)

WET

Tot wysiging van die Wet op Medisyne en Verwante Stowwe, 1965, ten einde sekere uitdrukkings te omskryf en sekere omskrywings te skrap of te wysig; vir die oogmerke en werksaamhede van die Owerheid voorsiening te maak; voorsiening te maak vir die samestelling, aanstelling van voorsitter, ondervoorsitter en lede, onbevoegdheid van lede, vergaderings en komitees van die Bestuur van die Owerheid; te vereis dat die Minister met die Pryskomitee oorleg pleeg by die voorskryf van aanvaarbare en verbode handelinge in verband met bonusgewing; die woord "produkte" met die woord "medisynes" en uitdrukking "gelyste stowwe" te vervang ten einde die onderwerp van die genoemde Wet korrek weer te gee; en om sekere tegniese verbeterings aan te bring; en om voorsiening te maak 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 vervang deur artikel 1 van Wet 65 van 1974 en gewysig deur artikel 1 van Wet 17 van 1979, artikel 1 van Wet 20 van 1981, artikel 1 van Wet 94 van 1991, artikel 1 van Wet 49 van 1996, artikel 1 van Wet 90 van 1997, artikel 1 van Wet 59 van 2002 en artikel 1 van Wet 72 van 2008

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

(a) wat in 'n nuusblad, tydskrif, pamflet, elektroniese media (met inbegrip van radio of televisie) 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 **[produk]** medisyne, gelyste stof, mediese toestel of IVD te bevorder, en het **'adverteer'** 'n ooreenstemmende betekenis;";

(b) deur die omskrywing van "advieskomitee" te skrap;

(c) by the insertion after the definition of ''Authority'' of the following definition:

'' **'Board'** means the Board referred to in section 2;'';

(d) by the deletion of the definition of ''cosmetic'';

(e) by the deletion of the definition of ''foodstuff'';

(f) by the substitution for the definition of ''IVD'' of the following definition:

'' '**IVD**' *(in vitro* **[*diagnostic medical device*]** diagnostic) means a medical device, whether used alone or in combination, intended by the manufacturer for the **[in-vitro]** *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 ''medicine'' of the following definition:

'' '**medicine**'—

(a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

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

(ii) restoring, correcting or modifying any somatic or psychic or organic function in humans; and

(b) includes any veterinary medicine;'';

(h) 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]** for *in vitro* use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)—

(a) intended by the manufacturer to be used, alone or in combination, for **[human beings]** humans or animals, for**[—]** one or more of the following:

(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, in or on the human or animal body, but which may be assisted in its intended function by such means;'';

(i) by the deletion of the definition of ''product''; and

(j) by the insertion after the definition of ''veterinary medicine'' of the following definition:

'' '**vigilance**', in relation to a medicine, medical device or IVD, means the continuous monitoring and evaluation of its safety, efficacy and performance profile and the management of any risk throughout its life-cycle.''.

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(c) deur die volgende omskrywing na die omskrywing van ''as geneesmiddel'' in te voeg:

'' **'Bestuur'** die Bestuur in artikel 2 bedoel;'';

(d) deur die volgende omskrywing na die omskrywing van ''inspekteur'' in te voeg:

'' **'IVD'** *(***[***in vitro***-diagnosties mediese toestel]** ***in vitro*****-diagnosties**) '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;'';

(e) 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]** vir *in vitro*-gebruik, sagteware, materiaal of ander soortgelyke of verwante artikel, ook Groep III- en IV- Gevaarhoudende Stowwe beoog in die Wet op Gevaarhoudende Stowwe, 1973 (Wet No. 15 van 1973)—

(a) wat deur die vervaardiger bedoel is vir gebruik, alleen of in kombinasie, vir mense of diere by**[—]** een of meer van die volgende:

(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 ondersteuring van die anatomie of van 'n fisiologiese proses;

(iv) ondersteuning of onderhoud 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 of dierlike liggaam bereik nie maar wat in sy beoogde werking op so 'n wyse aangehelp kan word.'';

(f) deur die omskrywing van ''medisyne'' deur die volgende omskrywing te vervang:

'' **'medisyne'—**

(a) enige stof of mengsel van stowwe wat gebruik word of geskik heet te wees vir gebruik of vervaardig of verkoop word vir gebruik by—

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

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

(b) ook enige veterinêre medisyne;'';

(g) deur die omskrywings van ''produk'', ''skoonheidsmiddel'' en ''voedselmiddel'' te skrap; en

(h) deur die volgende omskrywing na die omskrywing van ''voorgeskrewe'' in te voeg:

'' **'waaksaamheid'**, in verband met 'n medisyne, mediese toestel of IVD, voortgesette monitering en onderrig oor die veiligheid, doeltreffendheid en werkverrigtingsprofiel daarvan en die bestuur van enige risiko regdeur sy lewensiklus;''.

Amendment of section 2 of Act 101 of 1965, as substituted by section 2 of Act 72 of 2008

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

(a) by the substitution for the heading of the following heading:

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

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

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

(c) by the addition of the following subsection:

"(5) The Authority acts through its Board.".

Insertion of sections 2A to 2I in Act 101 of 1965

3. The following sections are hereby inserted in the principal Act after section 2:

"**Objects of Authority**

2A. The objects of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest.

Functions of Authority

2B. (1) The Authority must, in order to achieve its objects—

(a) ensure the efficient, effective and ethical evaluation or assessment and registration of medicines, medical devices and IVDs that meet defined standards of quality, safety, efficacy and performance, where applicable;

(b) ensure that the process of evaluating or assessing and registering medicines, medical devices and IVDs is transparent, fair, objective and concluded timeously;

(c) ensure the periodic re-evaluation or re-assessment and monitoring of medicines, medical devices and IVDs;

(d) ensure that evidence of existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance is being monitored, analysed and acted upon;

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

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

(2) The Authority may—

(a) liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of—

(i) matters of common interest; or

(ii) a specific investigation; and

(b) enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act.

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Wysiging van artikel 2 van Wet 101 van 1965, soos vervang deur artikel 2 van Wet 72 van 2008

2. Artikel 2 van die Hoofwet word hierby gewysig—

(a) deur die opskrif deur die volgende opskrif te vervang:

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

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

"(1) Die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte word hierby ingestel as 'n staatsorgaan binne die openbare administrasie, maar buite die staatsdiens."; en

(c) deur die volgende subartikel by te voeg:

"(5) Die Owerheid tree deur sy Bestuur op.".

Invoeging van artikels 2A tot 2I in Wet 101 van 1965

3. Die volgende artikels word hierby na artikel 2 in die Hoofwet ingevoeg:

"**Oogmerke van Owerheid**

2A. Die oogmerke van die Owerheid is om voorsiening te maak vir die monitering, evaluasie, regulering, ondersoek, inspeksie, registrasie en beheer van medisynes, gelyste stowwe, kliniese toetse en mediese toestelle, IVD's en verwante aangeleenthede in die openbare belang.

Werksaamhede van Owerheid

2B. (1) Die Owerheid moet, ten einde sy oogmerke te bereik—

(a) die doeltreffende, effektiewe en etiese evaluasie of assessering en registrasie van medisynes, mediese toestelle en IVD's wat aan omskrewe standaarde van gehalte, veiligheid, effektiwiteit en werkverrigting, waar van toepassing, voldoen, verseker;

(b) verseker dat die proses van evaluasie of assessering en registrasie van medisynes, mediese toestelle en IVD's deursigtig, billik, objektief en betyds afgehandel word;

(c) die periodieke herevaluasie of herassessering en monitering van medisynes, mediese toestelle en IVD's verseker;

(d) verseker dat bewyse van bestaande en nuwe nadelige gebeure, wisselwerkings, inligting oor waarneming en waaksaamheid ná bemarking gemonitor, geanaliseer en gebruik word;

(e) verseker dat voldoening aan bestaande wetgewing bevorder en beheer word deur 'n proses van aktiewe inspeksie en ondersoek; en

(f) verseker dat kliniese-proeweprotokolle volgens voorgeskrewe etiese en professionele maatstawwe en omskrewe standaarde geassesseer word.

(2) Die Owerheid kan—

(a) met enige ander reguleringsowerheid of -instelling skakel en kan, sonder om die algemeenheid van sy bevoegdheid te beperk, die nodige inligting vereis van, inligting uitruil met en inligting ontvang van enige sodanige owerheid of instelling ten opsigte van—

(i) aangeleenthede van gemeenskaplike belang; of

(ii) 'n bepaalde ondersoek; en

(b) ooreenkomste aangaan om met enige reguleringsowerheid saam te werk ten einde die oogmerke van hierdie Wet te bereik.

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Composition of Board

2C. (1) The Board of the Authority consists of not less than 10 but not more than 15 members appointed by the Minister.

(2) Subject to section 2D, the Minister must appoint as members of the Board—

(a) not more than 10 persons who have expertise in the fields of medicine, medical devices, IVD, vigilance, clinical trials, good manufacturing practice, public health or epidemiology;
(b) one person on account of his or her knowledge of the law;
(c) one person on account of his or her knowledge of good governance;
(d) one person on account of his or her knowledge of financial matters and accounting;
(e) one person on account of his or her knowledge of information technology; and
(f) one person on account of his or her knowledge of human resource management.

(3) The Chief Executive Officer is by virtue of his or her office a member of the Board but with no voting rights.

Appointment of members of Board

2D. (1) The Minister must, before appointing the members contemplated in section 2C(2), by notice in the *Gazette* and in two or more nationally circulating newspapers in the Republic, invite all interested persons to nominate, within the period specified in the notice, persons who in the opinion of such interested persons are fit to be so appointed, stating the grounds upon which such opinion is based.

(2) If the Minister receives no nominations or an insufficient number of nominations within the period specified in the notice referred to in subsection (1), the Minister may either readvertise or, in any other transparent manner, appoint the required number of qualified persons in terms of this Act.

(3) Subject to section 2F, a member of the Board—

(a) holds office for a minimum period of three years, but not exceeding five years, determined by the Minister at the time of the appointment of the member; and
(b) is eligible for re-appointment for one additional term.

(4) A member of the Board, excluding a member who is in the full-time employment of the State, must be appointed on such conditions as the Minister may, with the concurrence of the Minister of Finance, determine.

Appointment of chairperson and vice-chairperson of Board

2E. (1) The Minister must appoint a chairperson and vice-chairperson of the Board from among the members contemplated in section 2C(2).

(2) Whenever the chairperson of the Board is absent or unable to perform his or her functions as chairperson, the vice-chairperson must act as chairperson and if the vice-chairperson is absent or unable to act as chairperson the Minister must designate another member of the Board to act as chairperson until the chairperson or vice-chairperson is available.

(3) Any person acting as chairperson of the Board in terms of subsection (2) has all the powers and duties of the chairperson.

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Samestelling van Bestuur

2C. (1) Die Bestuur van die Owerheid bestaan uit minstens 10, maar hoogstens 15 lede deur die Minister aangestel.

(2) Behoudens artikel 2D, moet die Minister as lede van die Bestuur aanstel—

(a) hoogstens 10 persone met kundigheid in die velde van medisyne, mediese toestelle, IVD, waaksaamheid, kliniese proewe, goeie vervaardigingspraktyk, openbare gesondheid of epidemiologie;
(b) een persoon op grond van sy of haar regskennis;
(c) een persoon op grond van sy of haar kennis van goeie bestuur;
(d) een persoon op grond van sy of haar kennis van finansiële aangeleenthede en rekenpligtigheid;
(e) een persoon op grond van sy of haar kennis van inligtingstegnologie; en
(f) een persoon op grond van sy of haar kennis van mensehulpbronbestuur.

(3) Die Hoof- Uitvoerende Beampte is 'n lid van die Bestuur uit hoofde van sy of haar amp, maar het nie stemreg nie.

Aanstelling van lede van Bestuur

2D. (1) Die Minister moet, voor aanstelling van die lede in artikel 2C(2) beoog, by kennisgewing in die *Staatskoerant* en in twee of meer koerante met nasionale sirkulasie in die Republiek, alle belanghebbende persone nooi om binne die tydperk in die kennisgewing vermeld, persone te benoem wat na mening van sodanige belanghebbende persone geskik is om so aangestel te word, met die redes waarop sodanige mening gegrond is.

(2) Indien die Minister geen of te min benoemings binne die tydperk in die kennisgewing in subartikel (1) bedoel, ontvang nie, kan die Minister heradverteer of, op enige ander deursigtige wyse, die vereiste getal gekwalifiseerde persone ingevolge hierdie Wet aanstel.

(3) Behoudens artikel 2F—

(a) beklee 'n lid van die Bestuur die amp vir 'n minimum tydperk van drie jaar, maar hoogstens vyf jaar, bepaal deur die Minister ten tyde van die aanstelling van die lid; en
(b) kwalifiseer 'n lid van die Bestuur vir heraanstelling vir een bykomende termyn.

(4) 'n Lid van die Bestuur, met uitsondering van 'n lid wat voltyds in diens van die Staat is, moet op sodanige voorwaardes aangestel word wat die Minister, met die instemming van die Minister van Finansies, bepaal.

Aanstelling van voorsitter en ondervoorsitter van Bestuur

2E. (1) Die Minister moet 'n voorsitter en ondervoorsitter van die Bestuur uit die geledere van die lede in artikel 2C(2) beoog, aanstel.

(2) Wanneer die voorsitter van die Bestuur afwesig is of nie as voorsitter kan optree nie, moet die Minister 'n ander lid van die Bestuur aanwys om as voorsitter waar te neem totdat die voorsitter of ondervoorsitter beskikbaar is.

(3) Iemand wat ingevolge subartikel (2) as voorsitter van die Bestuur waarneem, het al die bevoegdhede en pligte van die voorsitter.

Disqualification from membership of Board and vacation of office

2F. (1) A person may not be appointed as a member of the Board if that person—

(a) is not a South African citizen and ordinarily resident in the Republic;
(b) is an unrehabilitated insolvent;
(c) has at any time been convicted of an offence involving dishonesty, whether in the Republic or elsewhere, and sentenced to imprisonment without the option of a fine; or
(d) has been removed from an office of trust.

(2) A member of the Board must vacate office if—

(a) he or she becomes disqualified in terms of subsection (1), from being appointed as a member of the Board;
(b) he or she submits his or her resignation to the Minister in writing;
(c) he or she is declared by the High Court to be of unsound mind or mentally disordered or is detained under the Mental Health Care Act, 2002 (Act No. 17 of 2002);
(d) he or she has, without the leave of the Board, been absent from more than two consecutive meetings of the Board; or
(e) the Minister, after consultation with the Board, withdraws the appointment of that member because the member is incompetent or unfit to fulfil his or her duties.

(3) If a member of the Board dies or vacates office in terms of subsection (2), the Minister may, subject to section 2D, appoint a person to fill the vacancy for the unexpired portion of the period for which that member was appointed.

Meetings of Board

2G. (1) The meetings of the Board and the conduct of business at meetings must be determined by the rules of the Board.

(2) A quorum for a meeting of the Board is the majority of its voting members.

(3) A decision of the majority of the members of the Board present at any meeting constitutes a decision of the Board and, in the event of an equality of votes, the member presiding at the meeting has a casting vote in addition to his or her deliberative vote.

(4) A decision taken by the Board or an act performed under the authority of the Board is not invalid by reason only of a vacancy on the Board, or that a person who is not entitled to sit as a member of the Board sat as a member at the time when the decision was taken or the act was authorised, if the decision was taken or the act was authorised by the requisite majority of the members of the Board who were present at the time and entitled to sit as members.

(5) Minutes of the proceedings of every meeting of the Board must be prepared and stored by such means as may be determined by the Board.

(6) Minutes of the proceedings of each meeting must be submitted at the next meeting of the Board and, if passed as correct, must be confirmed by the signature of the chairperson or other member presiding thereat and may, when so confirmed, be evidence in a court of law of the proceedings of the first-mentioned meeting.

(7) In the absence of the chairperson or the person acting as the chairperson from a particular meeting of the Board, the members present at that meeting may elect one of their number to preside at that meeting.

Committees of Board

2H. The Board may appoint one or more committees from among its members to assist it with the performance of its functions.

Onbevoegdheid vir lidmaatskap van Bestuur en ontruiming van amp

2F. (1) 'n Persoon mag nie as 'n lid van die Bestuur aangestel word nie as daardie persoon—

(a) nie 'n Suid-Afrikaanse burger is wat gewoonlik in die Republiek woonagtig is nie;
(b) 'n ongerehabiliteerde insolvent is;
(c) te eniger tyd skuldig bevind is aan 'n misdryf waarvan oneerlikheid 'n element is of aan 'n ander misdryf waarvoor hy of sy tot gevangenisstraf sonder die keuse van 'n boete gevonnis is; of
(d) van 'n vertrouensamp onthef is.

(2) 'n Lid van die Bestuur moet die amp ontruim indien—

(a) hy of sy ingevolge subartikel (1) onbevoeg word om as 'n lid van die Bestuur aangestel te word;
(b) hy of sy, sy of haar bedanking skriftelik by die Minister inhandig;
(c) hy of sy deur die Hooggeregshof as geestelik onbevoeg of geestesversteurd verklaar word of kragtens die 'Mental Health Care Act', 2002 (Wet No. 17 van 2002), aangehou word;
(d) hy of sy sonder verlof van die Bestuur van meer as twee opeenvolgende Bestuursvergaderings afwesig was; of
(e) die Minister, na oorleg met die Bestuur, die aanstelling van daardie lid intrek omdat die lid onbevoeg of ongeskik is om sy of haar pligte te verrig.

(3) Indien 'n lid van die Bestuur sterf of die amp ingevolge subartikel (2) ontruim, kan die Minister, behoudens artikel 2D, 'n persoon aanstel om die vakature te vul vir die onverstreke gedeelte van die tydperk waarvoor daardie lid aangestel is.

Vergaderings van Bestuur

2G. (1) Die vergaderings van die Bestuur en die verrigtinge by vergaderings moet deur die reëls van die Bestuur bepaal word.

(2) 'n Kworum vir 'n vergadering van die Bestuur is die meerderheid van sy lede met stemreg.

(3) 'n Besluit van die meerderheid van die lede van die Bestuur teenwoordig by enige vergadering is 'n besluit van die Bestuur en, in die geval van 'n staking van stemme het die lid wat oor die vergadering voorsit benewens sy of haar beraadslagende stem, ook 'n beslissende stem.

(4) 'n Besluit deur die Bestuur geneem of 'n handeling wat onder die gesag van die Bestuur uitgevoer is, is nie ongeldig bloot omdat daar 'n vakature op die Bestuur is nie, of omdat 'n persoon wat nie die reg het om as lid van die Bestuur te sit nie, as 'n lid van die Bestuur gesit het toe die besluit geneem is of die handeling gemagtig is, indien die besluit geneem is of die handeling gemagtig is deur die vereiste meerderheid van die lede van die Bestuur wat op daardie tydstip teenwoordig was en geregtig was om as lede te sit.

(5) Die notule van die verrigtinge van elke vergadering van die Bestuur moet voorberei word en op die wyse wat die Bestuur kan bepaal, geberg word.

(6) Die notule van die verrigtinge van elke vergadering moet by die volgende vergadering van die Bestuur voorgelê word en moet, indien dit as korrek aanvaar word, deur die handtekening van die voorsitter of ander lid wat oor die vergadering voorsit, bevestig word en kan, nadat dit aldus bevestig is, getuienis in 'n geregshof wees van die verrigtinge by die eersgenoemde vergadering.

(7) Indien die voorsitter of die persoon wat as voorsitter waarneem van 'n bepaalde vergadering van die Bestuur afwesig is, kan die teenwoordige lede by daardie vergadering iemand uit hul geledere verkies om by daardie vergadering voor te sit.

Komitees van Bestuur

2H. Die Bestuur kan een of meer komitees vanuit die geledere van sy lede aanstel om die Bestuur by te staan in die verrigting van die Bestuur se werksaamhede.

Dissolution of Board

2I. (1) The Minister may dissolve the Board if the Minister, on good cause shown, loses confidence in the ability of the Board to perform its functions effectively and efficiently.

(2) The Minister may dissolve the Board only—

(a) after having given the Board a reasonable opportunity to be heard; and
(b) after having afforded the Board a hearing on any submissions received.

(3) If the Minister dissolves the Board, the Minister—

(a) may appoint an administrator to take over the functions of the Board and to do anything which the Board might otherwise be empowered or required to do by or under this Act, subject to such conditions as the Minister may determine; and
(b) must, as soon as it is feasible but not later than three months after the dissolution of the Board, replace the members of the Board in the same manner in which they were appointed.

(4) The costs associated with the appointment of an administrator shall be for the account of the Authority.

(5) The appointment of the administrator terminates when the Board members have been replaced in terms of section 2C(2).''.

Amendment of section 3 of Act 101 of 1965, as substituted by section 3 of Act 72 of 2008

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

(a) by the substitution for subsection (1) of the following subsection:
''(1) The **[Minister]** Board, after consultation with the Minister, must appoint a suitably qualified person as the Chief Executive Officer of the Authority.'';
(b) by the substitution in subsection (4) for paragraphs *(b)* and *(c)* of the following paragraphs, respectively:
''*(b)* is appointed subject to the conclusion of a performance agreement with the **[Minister]** Board;
(c) is accountable to and reports to the **[Minister]** Board;''; and
(c) by the substitution for subsection (9) of the following subsection:
''(9) The Chief Executive Officer shall, in consultation with the Board, 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.''.

Repeal of section 4 of Act 101 of 1965

5. Section 4 of the principal Act is hereby repealed.

Substitution of section 13 of Act 101 of 1965, as substituted by section 6 of Act 72 of 2008

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

''**Registers**

13. (1) The Chief Executive Officer shall keep separate registers for **[products]** medicines, medical devices or IVDs **[;]**, in which he or she shall record—

(a) the registration of **[products]** medicines, medical devices or IVDs by the Authority; and
(b) such particulars in regard to the **[products]** medicines, medical devices or IVDs and the holder of certificate of registration in respect of such **[products]** medicines, medical devices or IVDs as are required by this Act.

13

Ontbinding van Bestuur

2I. (1) Die Minister kan die Bestuur ontbind indien die Minister, by die aanvoer van goeie gronde, vertroue verloor in die vermoë van die Bestuur om sy werksaamhede doeltreffend en effektief te verrig.

(2) Die Minister kan die Bestuur slegs ontbind—

(a) nadat die Bestuur 'n redelike kans gegun is om aangehoor te word; en

(b) nadat die Bestuur aangehoor is oor enige vertoë wat ontvang is.

(3) Indien die Minister die Bestuur ontbind—

(a) kan die Minister 'n administrateur aanstel om die werksaamhede van die Bestuur oor te neem en om enigiets te doen wat die Bestuur andersins deur of kragtens hierdie Wet gemagtig of vereis kon wees om te doen, behoudens die voorwaardes wat die Minister kan bepaal; en

(b) moet die Minister, sodra dit haalbaar is maar nie later nie as drie maande na die ontbinding van die Bestuur, die lede van die Bestuur vervang op dieselfde wyse waarop hulle aangestel is.

(4) Die uitgawes wat met die aanstelling van 'n administrateur gepaard gaan is vir die rekening van die Owerheid.

(5) Die aanstelling van die administrateur eindig wanneer die Bestuurslede ingevolge artikel 2C(2) vervang is.''.

Wysiging van artikel 3 van Wet 101 van 1965, soos vervang deur artikel 3 van Wet 72 van 2008

4. Artikel 3 van die Hoofwet word hierby gewysig—

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

''(1) Die **[Minister]** Bestuur, na oorleg met die Minister, stel 'n gepas gekwalifiseerde persoon aan as die Hoof- Uitvoerende Beampte van die Owerheid.'';

(b) deur in subartikel (4) paragrawe *(b)* en *(c)* onderskeidelik deur die volgende paragrawe te vervang:

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

(c) is aanspreeklik teenoor en doen verslag aan die **[Minister]** Bestuur;''; en

(c) deur subartikel (9) deur die volgende subartikel te vervang:

''(9) Die Hoof- Uitvoerende Beampte moet, in oorleg met die Bestuur, 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.''.

Herroeping van artikel 4 van Wet 101 van 1965

5. Artikel 4 van die Hoofwet word hierby herroep.

Vervanging van artikel 13 van Wet 101 van 1965, soos vervang deur artikel 6 van Wet 72 van 2008

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

''**Registers**

13. (1) Die Hoof- Uitvoerende Beampte moet afsonderlike registers hou vir **[produkte]** medisynes, mediese toestelle of IVD's, waarin hy of sy moet aanteken—

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

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

(2) The Chief Executive Officer shall publish on the Authority's website the registers referred to in subsection (1) and update those registers when registration is obtained.''.

Amendment of section 14 of Act 101 of 1965, as substituted by section 7 of Act 72 of 2008

7. Section 14 of the principal Act is hereby amended by the substitution in subsection (3) for paragraph *(b)* of the following paragraph:

''*(b)* if an application for the registration of such **[product]** medicine, 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 **[product]** medicine, medical device or IVD is published in the *Gazette* in terms of section **[15(10)]** 15(9) or section 17*(a)*.''.

Amendment of section 15 of Act 101 of 1965, as substituted by section 8 of Act 72 of 2008

8. Section 15 of the principal Act is hereby amended—

(a) by the insertion in subsection (3)*(a)* of the word ''and'' at the end of subparagraph (ii) and the substitution for subparagraph (iii) of the following subparagraph:

''(iii) is safe, efficacious and of good quality**[;]** and, in the case of a medical device and IVD, performs as intended.''.

(b) by the deletion in subsection (3)*(a)* of subparagraph (iv); and

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

''*(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]** reject the application.''.

Amendment of section 16 of Act 101 of 1965, as substituted by section 12 of Act 72 of 2008

9. Section 16 of the principal Act is hereby amended by the deletion in subsection (1) of the word ''or'' at the end of paragraph *(a)*, the insertion of the word ''or'' at the end of paragraph *(b)* and the addition of the following paragraph:

''*(c)* is of the opinion that it is not in the public interest that any medicine, medical device or IVD shall be available to the public,''.

Amendment of section 18 of Act 101 of 1965, as substituted by section 14 of Act 72 of 2008

10. Section 18 of the principal Act is hereby amended by the substitution for subsections (1) and (2) of the following subsections, respectively:

''(1) No person shall sell any **[product]**—

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

(b) medical device or IVD unless the medical device or IVD, or its packaging, bears a label, where practical, stating the prescribed particulars.

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

(2) Die Hoof- Uitvoerende Beampte publiseer die registers in subartikel (1) bedoel op die Owerheid se webtuiste en werk daardie registers by wanneer registrasie verkry word.''.

Wysiging van artikel 14 van Wet 101 van 1965, soos vervang deur artikel 7 van Wet 72 van 2008

7. Artikel 14 van die Hoofwet word hierby gewysig deur in subartikel (3) paragraaf *(b)* deur die volgende paragraaf te vervang:

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

Wysiging van artikel 15 van Wet 101 van 1965, soos vervang deur artikel 8 van Wet 72 van 2008

8. Artikel 15 van die Hoofwet word hierby gewysig—

(a) deur in subartikel (3)*(a)* die woord ''en'' aan die einde van subparagraaf (ii) in te voeg en subparagraaf (iii) deur die volgende subparagraaf te vervang:

''(iii) veilig, effektief en van goeie gehalte is**[;]** en, in die geval van 'n mediese toestel en IVD, werk soos beoog is.'';

(b) deur in subartikel (3)*(a)* subparagraaf (iv) te skrap; en

(c) deur in subartikel (3) paragraaf *(c)* deur die volgende paragraaf te vervang:

''*(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]** die aansoek weier.''.

Wysiging van artikel 16 van Wet 101 van 1965, soos vervang deur artikel 12 van Wet 72 van 2008

9. Artikel 16 van die Hoofwet word hierby gewysig deur in subartikel (1) die woord ''of'' aan die einde van paragraaf *(a)* te skrap, die woord ''of'' aan die einde van paragraaf *(b)* in te voeg en deur die volgende paragraaf by te voeg:

''*(c)* van oordeel is dat dit nie in die openbare belang is dat 'n medisyne, mediese toestel of IVD aan die publiek beskikbaar gestel word nie,''.

Wysiging van artikel 18 van Wet 101 van 1965, soos vervang deur artikel 14 van Wet 72 van 2008

10. Artikel 18 van die Hoofwet word hierby gewysig deur subartikels (1) en (2) onderskeidelik deur die volgende subartikels te vervang:

''(1) Niemand mag 'n **[produk]**—

(a) medisyne of gelyste stof verkoop nie tensy die onmiddellike houer of die pakket waarin daardie **[produk]** medisyne of gelyste stof verkoop word 'n etiket aan het waarop die voorgeskrewe besonderhede vermeld word; en

(b) mediese toestel of IVD verkoop nie tensy die mediese toestel of IVD, of die verpakking daarvan, waar prakties, 'n etiket aan het waarop die voorgeskrewe besonderhede vermeld word.

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

Substitution of section 18A in Act 101 of 1965, as substituted by section 15 of Act 72 of 2008

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

"**Bonusing**

18A. (1) No person shall supply any **[product]** medicine, 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) in consultation with the Pricing Committee referred to in section 22G.".

Amendment of section 19 of Act 101 of 1965, as substituted by section 18 of Act 72 of 2008

12. Section 19 of the principal Act is hereby amended by the substitution for subsection (2) of the following subsection:

"(2) The Authority may by notice in writing require any person who manufactures or sells **[products]** medicines, medical devices or IVDs or administers or prescribes any medicine, medical device or IVD or on whose direction any medicine or medical device 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 **[product]** medicine, medical device or IVD.".

Amendment of section 20 of Act 101 of 1965, as substituted by section 19 of Act 72 of 2008

13. Section 20 of the principal Act is hereby amended by the substitution in subsection (1) for paragraph *(b)* of the following paragraph:

"*(b)* in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any **[product]** medicine, medical device or IVD is other than that stated by the Authority in terms of **[sub-paragraph (ii) of paragraph *(a)* of section twenty-two]** section 22(1)*(a)*(ii) or state or suggest that any **[product]** medicine, medical device or IVD should be used for a purpose or under circumstances or manner other than that stated by the Authority in terms of **[subparagraph (iii) of paragraph *(a)* of that]** section 22(1)*(a)*(ii).".

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 and section 22 of Act 72 of 2008

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

(a) by the substitution for the heading of the following heading:

"**Control of medicines [and], Scheduled substances, medical devices and IVDs**"; and

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

"(1) Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine **[or]**, Scheduled substance, medical device or IVD, except in accordance with the prescribed conditions.".

Amendment of section 22B of Act 101 of 1965, as substituted by section 23 of Act 72 of 2008

15. Section 22B of the principal Act is hereby amended—

(a) by the substitution for the heading of the following heading:

"**Publication of information relating to [products] medicines, Scheduled substances, medical devices or IVDs**"; and

Vervanging van artikel 18A in Wet 101 van 1965, soos vervang deur artikel 15 van Wet 72 van 2008

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

"**Bonusgewing**

18A. Niemand mag 'n medisyne verskaf ooreenkomstig 'n bonusstelsel, kortingstelsel of enige ander aansporingskema nie.

(2) Ongeag subartikel (1), kan die Minister aanvaarbare en verbode handelinge in verband met subartikel (1) voorskryf in oorleg met die Pryskomitee in artikel 22G bedoel.".

Wysiging van artikel 19 van Wet 101 van 1965, soos vervang deur artikel 18 van Wet 72 van 2008

12. Artikel 19 van die Hoofwet word hierby gewysig deur subartikel (2) deur die volgende subartikel te vervang:

"(2) Die Owerheid kan by skriftelike kennisgewing enigiemand wat 'n **[produk]** medisyne, mediese toestel of IVD vervaardig of verkoop of 'n medisyne, mediese toestel of IVD toedien of voorskryf of op wie se lasgewing 'n medisyne of mediese toestel toegedien word, gelas om binne 'n tydperk in so 'n kennisgewing bepaal, aan die Owerheid inligting oor sodanige **[produk]** medisyne, 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.".

Wysiging van artikel 20 van Wet 101 van 1965, soos vervang deur artikel 19 van Wet 72 van 2008

13. Artikel 20 van die Hoofwet word hierby gewysig deur in subartikel (1) paragraaf *(b)* deur die volgende paragraaf te vervang:

"*(b)* in 'n advertensie 'n bewering maak ten effekte dat die terapeutiese doeltreffendheid en effek van 'n **[produk]** medisyne, mediese toestel of IVD, mediese toestel of IVD anders is as dié wat ingevolge **[subparagraaf (ii) van paragraaf *(a)* van artikel *twee-en-twintig*]** artikel 22(1)*(a)*(ii) deur die Owerheid vermeld is nie of verklaar of aan die hand doen dat 'n **[produk]** medisyne, 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 22(1)*(a)*(ii) deur die Owerheid vermeld is nie.".

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 en artikel 22 van Wet 72 van 2008

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

(a) deur die opskrif deur die volgende opskrif te vervang:

"**Beheer oor medisyne [en], gelyste stowwe, mediese toestelle en IVD's**"; en

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

"(1) Behoudens hierdie artikel mag niemand 'n medisyne **[of]**, gelyste stof, mediese toestel of IVD verkoop, in sy of haar besit hê of vervaardig nie behalwe ooreenkomstig die voorgeskrewe voorwaardes.".

Wysiging van artikel 22B van Wet 101 van 1965, soos vervang deur artikel 23 van Wet 72 van 2008

15. Artikel 22B van die Hoofwet word hierby gewysig—

(a) deur die opskrif deur die volgende opskrif te vervang:

"**Publikasie van inligting aangaande [produkte] medisynes, gelyste stowwe, mediese toestelle of IVD's**"; en

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

"(1) Notwithstanding the provisions of section 34 the 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 **[product]** medicine, Scheduled substance, medical device or IVD.".

Amendment of section 22C of Act 101 of 1965, as inserted by section 14 of Act 90 of 1997 and amended by section 6 of Act 59 of 2002 and section 24 of Act 72 of 2008

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

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

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

(b) the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a **[product]** medicine, Scheduled substance, medical device or IVD a licence to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such **[product]** medicine, Scheduled substance, 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 Authority may determine."; and

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

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

Amendment of section 22H of Act 101 of 1965, as inserted by section 14 of Act 90 of 1997 and amended by section 28 of Act 72 of 2008

17. Section 22H of the principal Act is hereby amended—

(a) by the substitution for the heading of the following heading:

"**Purchase and sale of medicines, medical devices, IVDs and Scheduled substances by wholesalers**"; and

(b) by the substitution for subsections (1) and (2) of the following subsections, respectively:

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

(b) A wholesaler shall—

(i) sell **[products]** medicines, medical devices or IVDs only into the retail sector; and

(ii) sell Scheduled substances to any person who may lawfully possess such substance.

[*(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 **[products]** medicines, medical devices or IVDs for credit purposes only, to the manufacturer or wholesaler from which **[that product was]** those medicines, medical devices or IVDs were initially obtained.".

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

"(1) Ondanks die bepalings van artikel 34 kan die 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 **[produk]** medisyne, gelyste stof, mediese toestel of IVD.".

Wysiging van artikel 22C van Wet 101 van 1965, soos ingevoeg deur artikel 14 van Wet 90 van 1997 en gewysig deur artikel 6 van Wet 59 van 2002 en artikel 24 van Wet 72 van 2008

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

(a) deur in subartikel (1) paragrawe *(a)* en *(b)* onderskeidelik deur die volgende paragrawe te vervang:

"*(a)* kan die Direkteur-generaal, op aansoek op die voorgeskrewe wyse en teen betaling van die voorgeskrewe gelde, 'n lisensie uitreik aan 'n geneesheer, tandarts, praktisyn, veearts, verpleegkundige of ander persoon wat kragtens die Wet op Gesondheidsberoepe, 1974 (Wet No. 56 van 1974), geregistreer is, om medisyne op te maak of toe te berei op die voorgeskrewe voorwaardes;

(b) kan die 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 **[produk]** medisyne, gelyste stof, mediese toestel of IVD, om daardie **[produk]** medisyne, gelyste stof, mediese toestel of IVD te vervaardig, in te voer, 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 Owerheid bepaal."; en

(b) 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 **[produk]** medisyne, gelyste stof, mediese toestel of IVD vervaardig, 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.".

Wysiging van artikel 22H van Wet 101 van 1965, soos ingevoeg deur artikel 14 van Wet 90 van 1997 en gewysig deur artikel 28 van Wet 72 van 2008

17. Artikel 22H van die Hoofwet word hierby gewysig—

(a) deur die opskrif deur die volgende opskrif te vervang:

"**Koop en verkoop van medisyne, mediese toestelle, IVD's en gelyste stowwe deur groothandelaars**"; en

(b) deur subartikels (1) en (2) onderskeidelik deur die volgende subartikels te vervang:

"(1) *(a)* 'n Groothandelaar mag nie **[produkte]** medisynes, gelyste stowwe, mediese toestelle of IVD's van enige ander bron as die oorspronklike vervaardiger of die primêre invoerder van die voltooide produk koop nie.

(b) 'n Groothandelaar mag—

(i) **[produkte]** medisynes, mediese toestelle of IVD's slegs in die kleinhandelsektor verkoop; en

(ii) gelyste stowwe slegs aan iemand verkoop wat sodanige stof wettig mag besit.

[*(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 **[produkte]** medisynes, mediese toestelle of IVD's, slegs vir kredietdoeleindes, aan die vervaardiger of groothandelaar van wie **[dit]** daardie medisynes, mediese toestelle of IVD's aanvanklik verkry is, belet nie.".

Amendment of section 28 of Act 101 of 1965, as amended by section 26 of Act 65 of 1974, section 12 of Act 17 of 1979, section 16 of Act 90 of 1997, section 11 of Act 59 of 2002 and section 35 of Act 72 of 2008

18. 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]** or dispense medicines or Scheduled substances, dispenses or handles **[products]** medicines, Scheduled substances, 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)*, *(c)* and *(d)* of the following paragraphs, respectively:

"*(b)* inspect any **[product]** medicine, Scheduled substance, 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]** medicine, Scheduled substance, 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;

(d) take so many samples of any such **[product]** medicine or Scheduled substance, 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.";

(c) by the substitution in subsection (2)*(a)* for subparagraph (i) of the following subparagraph:

"(i) be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such **[product]**medicine, Scheduled substance, 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;";

(d) by the substitution in subsection (2)*(a)* for subparagraph (iii) of the following subparagraph:

"(iii) then be transmitted to an analyst, pharmacologist, technician, **[or]** engineer, scientist, pathologist or expert designated by the Authority together with a certificate in the prescribed form signed by such inspector.";

(e) by the substitution in subsection (2) for paragraph *(b)* of the following paragraph:

"*(b)* A copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such **[product]** medicine, Scheduled substance, medical device or IVD or his or her agent."; and

(f) by the substitution for subsections (3) and (4) of the following subsections, respectively:

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

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

Wysiging van artikel 28 van Wet 101 van 1965, soos gewysig deur artikel 26 van Wet 65 van 1974, artikel 12 van Wet 17 van 1979, artikel 16 van Wet 90 van 1997, artikel 11 van Wet 59 van 2002 en artikel 35 van Wet 72 van 2008

18. Artikel 28 van die Hoofwet word hierby gewysig—

(a) deur in subartikel (1)*(a)* subparagraaf (i) 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]** of te resepteer, **[produkte]** medisynes, gelyste stowwe, mediese toestelle of IVD's te resepteer of te hanteer of van waar die houer van 'n lisensie soos beoog in artikel 22C(1)*(b)* 'n besigheid bedryf; of";

(b) deur paragrawe *(b)*, *(c)* en *(d)* onderskeidelik deur die volgende paragrawe te vervang:

"*(b)* enige **[produk]** medisyne, gelyste stof, 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]** medisyne, gelyste stof, 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;

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

(c) deur in subartikel (2)*(a)* subparagraaf (i) deur die volgende subparagraaf te vervang:

"(i) ooreenkomstig die voorgeskrewe metodes en in die teenwoordigheid van die persoon wat toesig het oor die **[produk]** medisyne, gelyste stof, 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;";

(d) deur in subartikel (2)*(a)* subparagraaf (iii) deur die volgende subparagraaf te vervang:

"(iii) dan gestuur word aan 'n ontleder, farmakoloog, tegnikus, **[of]** ingenieur, wetenskaplike, patoloog of kundige deur die Owerheid aangewys tesame met 'n sertifikaat in die voorgeskrewe vorm wat deur die inspekteur onderteken is.";

(e) deur in subartikel (2) paragraaf *(b)* deur die volgende paragraaf te vervang:

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

(f) deur subartikels (3) en (4) deur die volgende subartikel te vervang:

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

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

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, section 17 of Act 90 of 1997 and section 36 of Act 72 of 2008

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

(a) 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 **[product]** medicine, Scheduled substance, medical device or IVD—"; and

(b) by the substitution for paragraph (i) of the following paragraph:

"(i) sells any **[product]** medicine, Scheduled substance, medical device or IVD 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, section 18 of Act 90 of 1997 and section 37 of Act 72 of 2008

20. 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 **[product]** medicine, Scheduled substance, 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 **[product]** medicine, Scheduled substance, medical device or IVD forfeited under this Act shall be destroyed or otherwise dealt with as the 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, section 19 of Act 90 of 1997 and section 38 of Act 72 of 2008

21. 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 **[product]** medicine, Scheduled substance, 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 in subsection (1) 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 **[product]** medicine, Scheduled substance, 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 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.".

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, artikel 17 van Wet 90 van 1997 en artikel 36 van Wet 72 van 2008

19. Artikel 29 van die Hoofwet word hierby gewysig—

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

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

(b) deur paragraaf (i) deur die volgende paragraaf te vervang:

"(i) 'n **[produk,]** medisyne, gelyste stof, mediese toestel of IVD 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, artikel 18 van Wet 90 van 1997 en artikel 37 van Wet 72 van 2008

20. 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 **[produk]** medisyne, gelyste stof, 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 **[produk]** medisyne, gelyste stof, mediese toestel of IVD word vernietig of andersins mee gehandel soos die 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, artikel 19 van Wet 90 van 1997 en artikel 38 van Wet 72 van 2008

21. Artikel 31 van die Hoofwet word hierby gewysig—

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

"*(a)* word 'n hoeveelheid **[produkte]** medisyne, gelyste stof, mediese toestelle of IVD's wat in of op 'n perseel, plek, voertuig, vaartuig of 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 in subartikel (1) 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 **[produk]** medisyne, gelyste stof, 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 word, toelaatbaar by wyse van getuienis teen hom of haar as 'n erkenning van die feite uiteengesit in daardie verklaring of inskrywing, tensy 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.".

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 and section 41 of Act 72 of 2008

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

(a) by the substitution in subsection (1) for paragraphs (i) to (xi) of the following paragraphs, respectively:

"(i) prescribing the categories of persons by whom application may be made for the registration of any medicine, medical device or IVD or to whom a certificate of registration may be transferred;

(ii) prescribing the forms which shall be used for any application for the registration of any medicine, medical device or IVD and the particulars which shall be furnished with any such application (including particulars regarding the method by which the medicine, medical device or IVD in question or any component of such medicine, medical device or IVD is manufactured and the premises at which such medicine, medical device or IVD or any such component is manufactured);

(iii) providing for the classification of medicines, medical devices or IVDs into classes or categories for the purposes of this Act;

(iv) prescribing the samples of any medicine, medical device or IVD and the quantity thereof which shall accompany any application for the registration of a medicine, medical device or IVD;

(v) prescribing the form in which the medicines, medical devices or IVDs register shall be kept and the particulars which shall be entered therein in respect of any registered medicine, medical device or IVD, as the case may be;

(vi) prescribing the form of any certificate of registration of any medicine, medical device, or IVD;

(vii) prescribing the circumstances in which, the conditions on which and the persons or categories of persons to whom any medicine, **[or]** Scheduled substance, medical device or IVD may be sold;

(viii) prescribing the manner in which any package containing any medicine, **[or]** Scheduled substance, medical device or IVD shall be labelled, packed or sealed;

(ix) prescribing the particulars in regard to the use thereof which shall be furnished with any medicine, **[or]** Scheduled substance, medical device or IVD sold, and the manner in which such particulars shall be furnished;

(x) prescribing the particulars which shall appear in any advertisement relating to any medicine, **[or]** Scheduled substance, medical device or IVD, or prohibiting the inclusion of any specified particulars in such advertisement, or the distribution of any such advertisement to a specified person or a specified category of persons or to a specified organisation or a specified category of organisations;

(xi) prescribing the requirements with which any medicine, or any component thereof, medical device or IVD shall comply in regard to composition, therapeutic suitability and effect, purity or any other property;";

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

"(xv) prescribing the forms of licences, registers, prescription books, records and other documents which shall be kept or used in respect of medicines, Scheduled substances, medical devices or IVDs, the manner in which they shall be kept, the particulars which shall be entered therein and the place where and the period for which they shall be retained;";

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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 en artikel 41 van Wet 72 van 2008

22. Artikel 35 van die Hoofwet word hierby gewysig—

(a) deur in subartikel (1) paragrawe (i) tot (xi) onderskeidelik deur die volgende paragrawe te vervang:

"(i) wat die kategorieë persone voorskryf deur wie aansoek om die registrasie van 'n medisyne, mediese toestel of IVD gedoen of aan wie 'n registrasiesertifikaat oorgedra kan word;

(ii) wat die vorms wat by 'n aansoek om die registrasie van 'n medisyne, mediese toestel of IVD gebruik moet word en die besonderhede wat saam met so 'n aansoek verstrek moet word (met inbegrip van besonderhede betreffende die metode waarvolgens die betrokke medisyne, mediese toestel of IVD of 'n bestanddeel van daardie medisyne, mediese toestel of IVD vervaardig word en die perseel waarop dit vervaardig word), voorskryf;

(iii) wat voorsiening maak vir die indeling van **[medisyne]** medisynes, mediese toestelle of IVD's in klasse of kategorieë vir die doeleindes van hierdie Wet;

(iv) wat die monsters van enige medisyne, mediese toestel of IVD en die hoeveelheid daarvan wat 'n aansoek om die registrasie van 'n medisyne, mediese toestel of IVD moet vergesel, voorskryf;

(v) wat die vorm waarin die **[medisyneregister]** register van medisynes, mediese toestelle of IVD's gehou moet word en die besonderhede wat ten opsigte van enige geregistreerde medisyne, mediese toestel of IVD, na gelang van die geval, daarin aangeteken moet word, voorskryf;

(vi) wat die vorm van 'n registrasiesertifikaat van medisyne, mediese toestel of IVD voorskryf;

(vii) wat die omstandighede waarin, die voorwaardes waarop en die persone of klasse persone aan wie medisyne, **[of]** 'n gelyste stof, mediese toestel of IVD verkoop mag word, voorskryf;

(viii) wat die wyse waarop 'n pakket wat medisyne, **[of]** 'n gelyste stof, mediese toestel of IVD bevat, geëtiketteer, gepak of verseël moet word, voorskryf;

(ix) wat die besonderhede met betrekking tot die gebruik daarvan wat tesame met 'n medisyne, **[of]** gelyste stof, mediese toestel of IVD wat verkoop word, verstrek moet word en die wyse waarop sodanige besonderhede verstrek moet word, voorskryf;

(x) wat die besonderhede voorskryf wat in 'n advertensie betreffende 'n medisyne, **[of]** gelyste stof, mediese toestel of IVD moet verskyn, of wat die insluiting van bepaalde besonderhede in so 'n advertensie of die verspreiding van so 'n advertensie aan 'n bepaalde persoon of 'n bepaalde klas of kategorie van persone of aan 'n bepaalde organisasie of 'n bepaalde klas of kategorie van organisasies verbied;

(xi) wat die vereistes met betrekking tot die samestelling, terapeutiese bruikbaarheid en effek, suiwerheid of enige ander eienskap waaraan 'n medisyne, of bestanddeel daarvan, mediese toestel of IVD moet voldoen, voorskryf;";

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

"(xv) wat die vorms van lisensies, registers, voorskrifboeke, aantekeninge en ander stukke voorskryf wat ten opsigte van medisynes, gelyste stowwe, mediese toestelle of IVD's gehou of gebruik moet word, die wyse waarop hulle gehou moet word, die besonderhede wat daarin aangeteken moet word en die plek waar en die tydperk waarvoor hulle behou moet word;";

(c) by the substitution in subsection (1) for paragraphs (xvii), (xviii) and (xix) of the following paragraphs, respectively:

"(xvii) as to the transhipment or the exportation from or importation into the Republic of any medicine, Scheduled substance, medical device or IVD, specifying the ports or places at which such medicine, Scheduled substance, medical device or IVD may be brought into the Republic;

(xviii) authorising and regulating or restricting the transmission through the Republic of medicines, Scheduled substances, medical devices or IVDs;

(xix) prescribing the manner in which packages containing medicines, Scheduled substances, medical devices or IVDs shall be labelled when imported into or manufactured in the Republic and the persons by whom and the manner in which they shall be kept;";

(d) by the substitution in subsection (1) for paragraphs (xxii), (xxiii) and (xxiv) of the following paragraphs, respectively:

"(xxii) authorising and regulating the possession by persons entering or departing from the Republic of specified quantities of medicines, Scheduled substances, medical devices or IVDs for personal medicinal use;

(xxiii) as to the disposal or destruction of a medicine, **[or a]** Scheduled substance, medical device or IVD, and the records which shall be kept in respect thereof;

(xxiv) as to the importation, exportation, conveyance, keeping, storage, processing and packing of medicines, **[and]** Scheduled substances, medical devices or IVDs, and the manner in which medicines, **[and]** Scheduled substances, medical devices or IVDs shall be kept and controlled in different categories of hospitals;";

(e) by the substitution in subsection (1) for paragraphs (xxvii) to (xxxii) of the following paragraphs, respectively:

"(xxvii) authorising, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device, IVD or class of medical devices, IVDs or medicines in respect of its safety, quality and efficacy;

(xxviii) with regard to any matter to ensure the safety, quality and efficacy of medicines, **[and]** medical devices or IVDs;

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

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

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

(xxxii) prescribing the fee payable in respect of the authorisation of the use of unregistered medicines, medical devices or IVDs, the issuing of permits and certificates under this Act, the issuing or renewal of any licence under this Act, the performance of inspections to assess the safety, quality and efficacy of medicines, Scheduled substances, **[or]** medical devices or IVDs for the purpose of registration, **[and]** the evaluation of technical amendments and changes to the particulars contained in registers and the testing for batch release of biological medicines;";

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(c) deur in subartikel (1) paragrawe (xvii), (xviii) en (xix) onderskeidelik deur die volgende paragrawe te vervang:

“(xvii) aangaande die oorlaai of die uitvoer uit die Republiek of die invoer daarheen van enige medisyne, gelyste stof, mediese toestel of IVD met aangifte van die hawens of plekke waar sodanige medisyne, gelyste stof, mediese toestel of IVD in die Republiek ingebring kan word;

(xviii) wat die vervoer van medisynes, gelyste stowwe, mediese toestelle of IVD’s deur die Republiek magtig, reël of beperk;

(xix) wat die wyse voorskryf waarop pakkette wat medisynes, gelyste stowwe, mediese toestelle of IVD’s bevat, by invoer in die Republiek of vervaardiging in die Republiek geëtiketteer moet word en die persone deur wie en die wyse waarop hulle gehou moet word;”;

(d) deur in subartikel (1) paragrawe (xxii), (xxiii) en (xxiv) onderskeidelik deur die volgende paragrawe te vervang:

“(xxii) wat die besit, deur persone wat die Republiek binnekom of verlaat, van bepaalde hoeveelhede van medisynes, gelyste stowwe, mediese toestelle of IVD’s vir persoonlike medisinale gebruik, magtig en reël;

(xxiii) aangaande die beskikking oor of die vernietiging van ’n medisyne, **[of ’n]** gelyste stof, mediese toestel of IVD en die aantekeninge wat ten opsigte daarvan gehou moet word;

(xxiv) aangaande die invoer, uitvoer, vervoer, aanhouding, opslag, verwerking en verpakking van medisyne, **[en]** gelyste stowwe, mediese toestelle of IVD’s, en die wyse waarop medisyne, **[en]** gelyste stowwe, mediese toestelle of IVD’s in verskillende kategorieë hospitale aangehou en beheer moet word;”;

(e) deur in subartikel (1) paragrawe (xxvii) tot (xxxii) onderskeidelik deur die volgende paragrawe te vervang:

“(xxvii) wat die registrasie, vervaardiging, verandering, invoer, uitvoer, opslag, vervoer, verkoop of gebruik van enige mediese toestel, IVD of klas mediese toestelle, IVD’s of medisyne ten opsigte van die veiligheid, gehalte en doeltreffendheid daarvan, magtig, reël, beheer, beperk of verbied;

(xxviii) met betrekking tot ’n aangeleentheid om die veiligheid, gehalte en doeltreffendheid van medisyne, **[en]** mediese toestelle of IVD’s te verseker;

(xxix) aangaande die summiere beslaglegging op en beskikking oor enige medisyne, gelyste stof, mediese toestel of IVD wat in die besit of bewaring gevind word van iemand wat nie kragtens hierdie Wet daarop geregtig is om dit aan te hou of te gebruik nie;

(xxx) aangaande die beskikking oor of vernietiging van ’n medisyne, gelyste stof, mediese toestel of IVD wat onbruikbaar geword het, en die verslag wat ten opsigte daarvan verskaf moet word;

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

(xxxii) wat die geld voorskryf wat betaalbaar is ten opsigte van magtiging vir die gebruik van ongeregistreerde medisyne, mediese toestelle of IVD’s, die uitreik van permitte en sertifikate kragtens hierdie Wet, die uitreiking of hernuwing van ’n lisensie kragtens hierdie Wet, die uitvoer van inspeksies ten einde die veiligheid, gehalte en effektiwiteit van medisyne, gelyste stowwe, **[of]** mediese toestelle of IVD’s vas te stel vir doeleindes van registrasie, **[en]** die evaluering van tegniese wysigings en veranderinge aan besonderhede in registers en die toetsing vir lotvrystelling van biologiese medisyne;”;

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

"(xxxiv) relating to the conditions under which medicines, **[or]** Scheduled substances, medical devices or IVDs may be sold;";

(g) by the substitution in subsection (1) for paragraph (xxxviii) of the following paragraph:

"(xxxviii) relating to the safety, quality and efficacy of imported medicines, Scheduled substances, medical devices and IVDs;";

(h) by the substitution in subsection (1) for paragraphs (xl), (xli) and (xlii) of the following paragraphs, respectively:

"(xl) relating to **[products]** medicines, Scheduled substances, 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]** medicines, Scheduled substances, medical devices and IVDs in general;

(xlii) relating to the licensing for possessing or using certain **[products]** medicines, Scheduled substances, medical devices or IVDs;"; and

(i) by the substitution for subsections (5) and (6) of the following subsections, respectively:

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

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

Substitution of section 36 of Act 101 of 1965, as substituted by section 42 of Act 72 of 2008

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

"**Exclusion of any [product] medicine, Scheduled substance, 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]** medicine, Schedule substance, 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]** medicine or Scheduled substance from the operation of **[section]** sections 18A and 22G shall be effected by the Minister on the recommendation of the Pricing Committee.".

Substitution of certain words in Act 101 of 1965

24. The principal Act is hereby amended by the substitution for the words "product" and "products", wherever they occur except in sections 2, 22A, 22F(4)*(c)* and 22H(1)*(a)* and Schedules 0 up to and including 6, of the words "medicine" and "medicines", respectively.

(f) deur in subartikel (1) paragraaf (xxxiv) deur die volgende paragraaf te vervang:

"(xxxiv) betreffende die voorwaardes waarop medisyne, **[of]** gelyste stowwe, mediese toestelle of IVD's verkoop mag word;";

(g) deur in subartikel (1) paragraaf (xxxviii) deur die volgende paragraaf te vervang:

"(xxxviii) betreffende die veiligheid, gehalte en doeltreffendheid van ingevoerde medisyne, gelyste stowwe, mediese toestelle en IVD's;";

(h) deur in subartikel (1) paragrawe (xl), (xli) en (xlii) onderskeidelik deur die volgende paragrawe te vervang:

"(xl) betreffende **[produkte]** medisynes, gelyste stowwe, 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]** medisynes, gelyste stowwe, mediese toestelle en IVD's oor die algemeen;

(xlii) betreffende die lisensiëring vir die besit of gebruik van sekere **[produkte]** medisynes, gelyste stowwe, mediese toestelle of IVD's;"; en

(i) deur subartikels (5) en (6) deur die volgende subartikels te vervang:

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

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

Vervanging van artikel 36 van Wet 101 van 1965, soos vervang deur artikel 42 van Wet 72 van 2008

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

"**Uitsluiting van enige [produk] medisyne, gelyste stof, 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]** medisyne, gelyste stof, 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]** medisyne of gelyste stof van die toepassing van **[artikel]** artikels 18A en 22G deur die Minister, op aanbeveling van die Pryskomitee, uitgevoer word.".

Vervanging van sekere woorde in Wet 101 van 1965

24. Die Hoofwet word hierby gewysig deur die woorde "produk" en "produkte", waar hulle ook al voorkom buiten in artikels 2, 22A, 22F(4)*(c)* en 22H(1)*(a)* en Bylaes 0 tot en met 6, onderskeidelik deur die woorde "medisyne" en "medisynes" te vervang.

Repeal of law

25. Section 44 of the Medicines and Related Substances Amendment Act, 2008 (Act No. 72 of 2008), is hereby repealed.

Transitional provisions

26. (1) For the purposes of this section—

(a) ''Authority'' means the South African Health Products Regulatory Authority established by section 2 of the principal Act as amended by this Act;
(b) ''commencement date'' means the date on which this Act takes effect;
(c) ''Council'' means the Medicines Control Council established by section 2 of the principal Act; and
(d) ''Department'' means the national Department of Health.

(2) *(a)* The Council continues to perform the functions which it performed before the commencement date but ceases to exist the day immediately before the date of the first meeting of the Board appointed by the Minister of Health in terms of section 2C of the principal Act as amended by this Act.

(b) The date of the first meeting of the Board referred to paragraph *(a)* must be determined by the Minister.

(c) Anything done by the Council that could have been done by the Authority in terms of the principal Act as amended by this Act must be regarded as having been done by the Authority.

(3) Medicines, medical devices and IVDs that are registered on the commencement date must be regarded as having been registered in terms of the principal Act as amended by this Act and the Chief Executive Officer must enter them in the relevant register.

(4) *(a)* The Minister of Health must, at least 30 days before the commencement date, designate all the employees of the Department who are engaged in the regulation of medicines and health technologies and in radiation control as employees to be transferred to the Authority.

(b) An employee contemplated in paragraph *(a)* must be informed in writing of the designation as soon as possible after designation.

(c) The transfer of the designated employees must be in accordance and subject to—

(i) the relevant labour legislation;
(ii) the Public Service Act, 1994 (Proclamation No. 103 of 1994); and
(iii) any collective agreement reached between employers and employees.

(d) For the purposes of the Income Tax Act, 1962 (Act No. 58 of 1962), no change of employer must be regarded as having taken place when employment is taken up at the Authority by a person contemplated in this subsection.

(e) Any person transferred to the Authority in terms of this subsection remains subject to any decision, proceeding, ruling and direction applicable to that person immediately before the transfer date to the extent that such decision, proceeding, ruling and direction remain applicable.

(f) Any proceedings against a person transferred to the Authority that were pending immediately before the transfer date must be disposed of as if that person had not been transferred.

(5) *(a)* Registration of any medicine, medical device or IVD which was pending registration before the commencement date, must be dealt with by the Authority as if this Act has not been passed.

(b) Any appeal in terms of section 24 of the principal Act that is pending on the commencement date must be dealt with as if this Act had not been passed.

(c) Decisions, guidelines and procedures made and adopted by the Department that are in force on the commencement date and that deals with matters in respect of which the Authority may make rules and guidelines in terms of the principal Act as amended by this Act, remain in force until amended or repealed by the Authority.

(6) *(a)* The ownership and control of all movable property of which the ownership and control vested in the State immediately before the commencement date and which has been used for the purposes or in connection with the exercise or performance of the powers and duties of the employees transferred to the Authority in terms of this section must be transferred to the Authority.

Herroeping van Wet

25. Artikel 44 van die Wysigingswet op Medisyne en Verwante Stowwe, 2008 (Wet No. 72 van 2008), word hierby herroep.

Oorgangsbepalings

26. (1) By die toepassing van hierdie artikel beteken—

(a) ''Owerheid'' die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte ingestel by artikel 2 van die Hoofwet soos deur hierdie Wet gewysig;

(b) ''inwerkingtredingsdatum'' die datum waarop hierdie Wet van krag word;

(c) ''Raad'' die Medisynebeheerraad deur artikel 2 van die Hoofwet ingestel; en

(d) ''Departement'' die nasionale Departement van Gesondheid.

(2) *(a)* Die Raad gaan voort om die werksaamhede te verrig wat dit voor die inwerkingtredingsdatum verrig het, maar hou op bestaan onmiddellik voor die datum van die eerste vergadering van die Bestuur deur die Minister van Gesondheid aangestel ingevolge artikel 2C van die Hoofwet soos deur hierdie Wet gewysig.

(b) Die datum van die eerste vergadering van die Raad in paragraaf *(a)* bedoel moet deur die Minister bepaal word.

(c) Enigiets wat die deur die Raad gedoen is wat deur die Owerheid ingevolge die Hoofwet soos deur hierdie Wet gewysig, gedoen sou kon wees, moet geag word deur die Owerheid gedoen te wees.

(3) Medisynes, mediese toestelle en IVD's wat op die inwerkingtredingsdatum reeds geregistreer is, moet geag word ingevolge die Hoofwet soos deur hierdie Wet gewysig geregistreer te wees en die Hoof- Uitvoerende Beampte moet dit in die tersaaklike register opneem.

(4) *(a)* Die Minister van Gesondheid moet, ten minste 30 dae voor die inwerkingtredingsdatum, al die werknemers van die Departement wat by die regulering van medisynes en gesondheidstegnologieë en in bestralingsbeheer betrokke is, aanwys as werknemers wat na die Owerheid oorgeplaas moet word.

(b) 'n Werknemer in paragraaf *(a)* beoog moet so gou as moontlik na die aanwysing skriftelik daarvan verwittig word.

(c) Die oordrag van die aangewese werknemers moet geskied ooreenkomstig en behoudens—

(i) die tersaaklike arbeidswetgewing;

(ii) die Staatsdienswet, 1994 (Proklamasie No. 103 van 1994); en

(iii) enige kollektiewe ooreenkoms aangegaan tussen werkgewers en werknemers.

(d) Vir die doeleindes van die Wet op Inkomstebelasting, 1962 (Wet No. 58 van 1962), moet geag word dat geen verandering van werkgewer geskied het nie wanneer 'n persoon in hierdie subartikel beoog by die Owerheid begin werk nie.

(e) Enige persoon ingevolge hierdie subartikel na die Owerheid oorgeplaas bly onderworpe aan enige besluit, verrigting, beslissing en lasgewing van toepassing op daardie persoon onmiddellik voor die oordragdatum in soverre daardie besluit, verrigting, beslissing en lasgewing steeds van toepassing is.

(f) Enige verrigtinge teen 'n persoon wat na die Owerheid oorgeplaas is wat onmiddellik voor die oordragdatum hangende was, moet oor beskik word asof daardie persoon nie oorgeplaas is nie.

(5) *(a)* Registrasie van enige medisyne, mediese toestel of IVD wat voor die inwerkingtredingsdatum hangende was, moet deur die Owerheid hanteer word asof hierdie Wet nie deurgevoer is nie.

(b) Enige appèl ingevolge artikel 24 van die Hoofwet wat op die inwerkingtredingsdatum hangende is, moet hanteer word asof hierdie Wet nie deurgevoer is nie.

(c) Besluite, riglyne en prosedures gemaak en aangeneem deur die Departement wat op die inwerkingtredingsdatum van krag is en wat handel oor die aangeleenthede ten opsigte waarvan die Owerheid reëls en riglyne ingevolge die Hoofwet soos deur hierdie Wet gewysig mag maak, bly van krag totdat dit deur die Owerheid gewysig of herroep word.

(6) *(a)* Die eienaarskap en beheer van alle roerende eiendom waarvan die eienaarskap en beheer onmiddellik voor die inwerkingtredingsdatum in die staat gevestig het en wat gebruik is vir die doeleindes van of in verband met die uitoefening of verrigting van die bevoegdhede en pligte van die werknemers wat ingevolge hierdie artikel na die Owerheid oorgeplaas is, moet na die Owerheid oorgedra word.

(b) In the event of the movable property being held under a lease or pledge or any form of security, such lease or pledge or other security are transferred on the commencement date to the Authority.

(c) On production of a certified register by the Director-General of the Department that movable property that constitutes part of the resources of the employees contemplated in subsection (4)*(a)* is owned by the State, the Authority must make such entries or endorsements in or on any relevant register or other document to register that movable property in its name, and the Director-General must remove that removable property from its asset register.

(d) From the commencement date all contractual rights, obligations, assets and liabilities of the Department in respect of that part of the Department under which the employees contemplated in subsection (4)*(a)* fall vest in and must be transferred to the Authority.

(e) Any litigation resulting from any cause of action in relation to the assets, rights, obligations or liabilities transferred to the Authority in terms of paragraph *(a)* which arose—

(i) before the commencement date, must be conducted by or against the Department; and

(ii) on or after the commencement date must be conducted by or against the Authority.

(f) If there is any uncertainty about which movable property must be transferred to the Authority, the matter must be finally determined by the Minister, in consultation with the Minister of Finance.

(7) The fees to be charged by the Authority for services rendered to any applicant in respect of any medicine, Scheduled substance, medical device and IVD must, from the commencement date, be as contained in the regulations in force and used by the Department immediately before the commencement date until the relevant regulations have been amended or substituted by the Minister in terms of the principal Act as amended by this Act.

(8) *(a)* All debt owing to the Department for medicines regulation immediately before the date of commencement of this Act is payable to the Authority and must be managed under the same conditions that applied immediately prior to that commencement date.

(b) The Authority may alter the conditions under which the debt is managed after giving the debtors three months notice of the proposed changes.

(c) The bank account held by the Department for medicine regulation and all amounts in the account must be transferred to the Authority on the commencement date.

Short title and commencement

27. This Act is called the Medicines and Related Substances Amendment Act, 2015, and comes into operation immediately after the commencement of the Medicines and Related Substances Amendment Act, 2008 (Act No. 72 of 2008).

(b) Indien roerende eiendom in huurpag of pand of enige vorm van sekuriteit gehou word, word die huurpag of pand of ander sekuriteit op die oordragdatum na die Owerheid oorgedra.

(c) By voorlegging van 'n gesertifiseerde register deur die Direkteur-generaal van die Departement dat roerende eiendom wat deel uitmaak van die hulpbronne van die werknemers in subartikel (4)*(a)* beoog die eiendom van die Staat is, moet die Owerheid sodanige inskrywings of endosserings in of op enige tersaaklike register of ander dokument maak om daardie roerende eiendom in sy naam te registreer, en die Direkteur-generaal moet daardie roerende eiendom van sy bateregister verwyder.

(d) Vanaf die inwerkingtredingsdatum vestig alle kontraktuele regte, bates en laste van die Departement ten opsigte van daardie deel van die Departement waaronder die werknemers in subartikel (4)*(a)* beoog, val, in die Owerheid en moet dit na die Owerheid oorgedra word.

(e) Enige gedinge na aanleiding van enige skuldoorsaak in verband met die regte, verpligtinge of laste wat ingevolge paragraaf *(a)* na die Owerheid oorgedra is wat ontstaan het—

(i) voor die inwerkingtredingsdatum, moet deur of teen die Departement gevoer word; en

(ii) op of na die inwerkingtredingsdatum, moet deur of teen die Owerheid gevoer word.

(f) Indien daar enige onsekerheid bestaan oor watter roerende eiendom na die Owerheid oorgedra moet word, moet die aangeleentheid finaal deur die Minister bepaal word, in oorleg met die Minister van Finansies.

(7) Die geld wat deur die Owerheid gehef word vir dienste gelewer aan enige aansoeker ten opsigte van enige medisyne, gelyste stof, mediese toestel en IVD moet, vanaf die inwerkingtredingsdatum, wees soos vervat in die regulasies wat van krag is en wat deur die Departement gebruik is net voor die inwerkingtredingsdatum totdat die tersaaklike regulasies ingevolge die Hoofwet soos deur hierdie Wet gewysig, vervang of gewysig is.

(8) *(a)* Alle skuld wat onmiddellik voor die inwerkingtredingsdatum van hierdie Wet aan die Departement verskuldig is vir medisyneregulasie, is aan die Owerheid betaalbaar en moet kragtens dieselfde voorwaardes wat onmiddellik voor daardie inwerkingtredingsdatum van toepassing was, bestuur word.

(b) Die Owerheid kan die voorwaardes waarkragtens die skuld bestuur word, verander nadat die skuldenaars drie maande kennis van die voorgestelde veranderinge gegee is.

(c) Die Departement se bankrekening vir medisyneregulering en alle bedrae in die rekening moet op die inwerkingtredingsdatum na die Owerheid oorgedra word.

Kort titel en inwerkingtreding

27. Hierdie Wet heet die Wysigingswet op Medisyne en Verwante Stowwe, 2015, en tree in werking onmiddellik na die inwerkingtreding van die Wysigingswet op Medisyne en Verwante Stowwe, 2008 (Wet No. 72 van 2008).