MEDICINES AND RELATED SUBSTANCES ACT
NO. 101 OF 1965

[View Regulation]

[ASSENTED TO 19 JUNE, 1965]
[DATE OF COMMENCEMENT: 1 APRIL, 1966]

(Afrikaans text signed by the State President)

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as amended by

Drugs Control Amendment Act, No. 29 of 1968

Drugs Control Amendment Act, No. 88 of 1970

Drugs Laws Amendment Act, No. 95 of 1971

Drugs Control Amendment Act, No. 65 of 1974

Medicines and Related Substances Control Amendment Act, No. 19 of 1976

Health Laws Amendment Act, No. 36 of 1977

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

Medicines and Related Substances Control Amendment Act, No. 20 of 1981

Transfer of Powers and Duties of the State President Act, No. 97 of 1986
[with effect from 3 October, 1986]

Businesses Act, No. 71 of 1991
[with effect from 24 May, 1991]

Medicines and Related Substances Control Amendment Act, No. 94 of 1991

General Law Amendment Act, No. 49 of 1996
[with effect from 4 October, 1996]

Abolition of Restrictions on the Jurisdiction of Courts Act, No. 88 of 1996
[with effect from 22 November, 1996]

Medicines and Related Substances Control Amendment Act, No. 90 of 1997

Medicines and Related Substances Amendment Act, No. 59 of 2002

Judicial Matters Amendment Act, No. 66 of 2008
[with effect from 17 February, 2009]

Medicines and Related Substances Amendment Act No. 72 of 2008

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

GENERAL NOTE

There is a discrepancy between the English and Afrikaans texts of section 1 of Act No. 94 of 1991, which affects section 1 of this Act.

The definition of "landdros" in section 1 of the Afrikaans text of this Act has been amended by the Judicial Matters Amendment Act, No. 66 of 2008. We suggest that reference be made to the Afrikaans Act for this definition.

In terms of s. 24 **of** Act No. 14 of 2015**, 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, are substituted by the words "medicine" and "medicines", respectively.**

EDITORIAL NOTE

Please note that details of Government Notices published in *Government Gazettes* that amend the Schedules to the Act are annotated at the beginning of the Schedules.

ACT

To provide for the registration of medicines and related substances intended for human and for animal use; to provide for the establishment of a Medicines Control Council; to provide that such council shall be a juristic person; to make other provision for the constitution of the council; to provide that a member of the council or committee shall declare his or her commercial interest related to the pharmaceutical or health care industry; to provide that the appointment of members of the executive committee is subject to the approval of the Minister; to provide for the control of medicines and scheduled substances and medical devices; to make further provision for the prohibition on the sale of medicines which are subject to registration and are not registered; to provide for procedures that will expedite the registration of essential medicines, and for the re-evaluation of all medicines after five years; to provide for measures for the supply of more affordable medicines in certain circumstances; to provide that labels be approved by the council; to prohibit sampling and bonusing of medicines; to provide for the licensing of certain persons to compound, dispense or manufacture medicines and medical devices and also to act as wholesalers or distributors; to provide for the generic substitution of medicines; to provide for the establishment of a pricing committee; to regulate the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines; to make new provisions for appeals against decisions of the Director-General or the council; to provide that the council may acquire and appropriate funds; to regulate the Minister's power to make regulations; to provide for the rationalization of certain laws relating to medicines and related substances that have remained in force in various territories on the national territory of the Republic by virtue of item 2 of Schedule 6 to the Constitution of the Republic of South Africa, 1996; and to provide for matters connected therewith.

[Long title substituted by s. 37 of Act No. 65 of 1974, by s. 15 of Act No. 17 of 1979, by s. 22 of Act No. 94 of 1991, by s. 29 of Act No. 90 of 1997 and by s. 13 of Act No. 59 of 2002.]

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1. Definitions.—(1) In this Act, unless the context otherwise indicates—

"advertisement", in relation to any 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 medicine, Scheduled substance, medical device or IVD, and **"advertise"** has a corresponding meaning;

[Definition of "advertisement" amended by s. 1 (a) of Act No. 20 of 1981 and substituted by s. 1 (a) of Act No. 72 of 2008 and by s. 1 (a) of Act No. 14 of 2015.]

"advisory committee" . . . . . .

[Definition of "advisory committee" inserted by s. 1 (a) of Act No. 72 of 2008. (Editorial Note: S. 1 (a) of Act No. 72 of 2008 does not give instructions to insert the definition of "advisory committee", however we suggest this was intended) and deleted by s. 1 (b) of Act No. 14 of 2015.]

"analyst" means an analyst to whom authority has been granted under section 27;

"appeal board" . . . . . .

[Definition of "appeal board" deleted by s. 1 (a) of Act No. 94 of 1991.]

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

[Definition of "approved name" substituted by s. 1 (a) of Act No. 90 of 1997.]

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

[Definition of "Authority" inserted by s. 1 (b) of Act No. 72 of 2008.]

"Board" means the Board referred to in section 2;

[Definition of "Board" inserted by s. 1 (c) of Act No. 14 of 2015.]

"certificate of registration" means a certificate of registration issued under section 15 (4), 15A (4) or 15B (4);

[Definition of "certificate of registration" inserted by s. 1 (b) of Act No. 20 of 1981.]

"cosmetic" . . . . . .

[Definition of "cosmetic" inserted by s. 1 (c) of Act No. 72 of 2008 and deleted by s. 1 (d) of Act No. 14 of 2015.]

"council" . . . . . .

[Definition of "council" deleted by s. 1 (d) of Act No. 72 of 2008.]

"dentist" means a person registered as such under the Health Professions Act, 1974;

[Definition of "dentist" substituted by s. 1 (b) of Act No. 90 of 1997.]

"Director-General" means the Director-General: Health;

[Definition of "Director-General" inserted by s. 1 (c) of Act No. 20 of 1981 and substituted by s. 1 (b) of Act No. 94 of 1991 and by s. 1 (c) of Act No. 90 of 1997.]

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

[Definition of "export" inserted by s. 1 (a) of Act No. 17 of 1979.]

"foodstuff" . . . . . .

[Definition of "foodstuff" inserted by s. 1 (e) of Act No. 72 of 2008 and deleted by s. 1 (e) of Act No. 14 of 2015.]

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

"immediate container", in relation to a medicine or Scheduled substance, means a container which is in direct contact with the medicine or substance;

[Definition of "immediate container" inserted by s. 1 (b) of Act No. 17 of 1979.]

"inspector" means a person authorized as such under section 26;

"interchangeable multi-source medicine" means medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed;

[Definition of "interchangeable multi-source medicine" inserted by s. 1 (d) of Act No. 90 of 1997.]

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

provide information for diagnostic, monitoring or compatibility purposes;

[Definition of "IVD" inserted by s. 1 (f) of Act No. 72 of 2008 and substituted by s. 1 (f) of Act No. 14 of 2015.]

"label", when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun, means any brand or mark or any written, pictorial or other descriptive matter appearing on or attached to or packed with and referring to any article or the package containing any article;

"magistrate" means a magistrate as defined in section 1 of the Magistrates Act, 1993 (Act No. 90 of 1993), and includes an additional magistrate and an assistant magistrate;

[Definition of "magistrate" inserted by s. 1 (a) of Act No. 59 of 2002.]

"Medical Act" . . . . . .

[Definition of "Medical Act" deleted by s. 1 (e) of Act No. 90 of 1997.]

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent 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 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 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;

[Definition of "medical device" inserted by s. 1 (c) of Act No. 94 of 1991 and substituted by s. 1 (g) of Act No. 72 of 2008 and by s. 1 (h) of Act No. 14 of 2015.]

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

[Definition of "medical device or IVD establishment" inserted by s. 1 (h) of Act No. 72 of 2008.]

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

[Definition of "medical practitioner" substituted by s. 1 (c) of Act No. 17 of 1979, by s. 1 (d) of Act No. 94 of 1991 and by s. 1 (f) of Act No. 90 of 1997.]

"medicinal purpose" . . . . . .

[Definition of "medicinal purpose" deleted by s. 1 (e) of Act No. 94 of 1991.]

"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;

[Definition of "medicine" substituted by s. 1 (d) of Act No. 17 of 1979, by s. 1 (i) of Act No. 72 of 2008 and by s. 1 (g) of Act No. 14 of 2015.]

"Minister" means the Minister of Health;

[Definition of "Minister" substituted by s. 1 (d) of Act No. 20 of 1981, by s. 1 (f) of Act No. 94 of 1991 and by s. 1 (g) of Act No. 90 of 1997.]

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

[Definition of "nurse" inserted by s. 1 (g) of Act No. 94 of 1991.]

"package" means anything in or by which any medicine or Scheduled substance is enclosed, covered, contained or packed;

"pathologist" means a pathologist to whom authority has been granted under section 27;

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

[Definition of "pharmacist" substituted by s. 1 (e) of Act No. 17 of 1979 and by s. 1 (h) of Act No. 94 of 1991.]

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

[Definition of "pharmacist intern" inserted by s. 1 (h) of Act No. 90 of 1997.]

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

[Definition of "pharmacist's assistant" inserted by s. 1 (f) of Act No. 17 of 1979, deleted by s. 1 (i) of Act No. 94 of 1991 and inserted by s. 1 (h) of Act No. 90 of 1997.]

"pharmacologist", except for the purposes of section 24 (1) (c), means a pharmacologist to whom authority has been granted under section 27;

[Definition of "pharmacologist" substituted by s. 1 (j) of Act No. 94 of 1991.]

"pharmacy Board" . . . . . .

[Definition of "pharmacy Board" deleted by s. 1 (k) of Act No. 94 of 1991.]

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

[Definition of "practitioner" inserted by s. 1 (l) of Act No. 94 of 1991 and substituted by s. 1 (i) of Act No. 90 of 1997 and by s. 1 (b) of Act No. 59 of 2002.]

"prescribed" means prescribed by or under this Act;

"product" . . . . . .

[Definition of "product" inserted by s. 1 (j) of Act No. 72 of 2008 and deleted by s. 1 (i) of Act No. 14 of 2015.]

"public" includes a section of the public concerned with manufacturing, dispensing, selling or administering, or the issue of prescriptions for, medicines or a Scheduled substance;

[Definition of "public" inserted by s. 1 (e) of Act No. 20 of 1981.]

"register", when used as a noun, means the register referred to in section 13, and when used as a verb, means to enter in such register;

"registered" means entered in the register;

"registrar" " . . . . . .

[Definition of "registrar" deleted by s. 1 (k) of Act No. 72 of 2008.]

"regulation" means a regulation made and in force under this Act;

"Scheduled substance" means any medicine or other substance prescribed by the Minister under section 22A;

[Definition of "Scheduled substance" substituted by s. 1 (m) of Act No. 94 of 1991.]

"Schedule 1 substance" . . . . . .

[Definition of "Schedule 1 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 2 substance" . . . . . .

[Definition of "Schedule 2 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 3 substance" . . . . . .

[Definition of "Schedule 3 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 4 substance" . . . . . .

[Definition of "Schedule 4 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 5 substance" . . . . . .

[Definition of "Schedule 5 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 6 substance" . . . . . .

[Definition of "Schedule 6 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 7 substance" . . . . . .

[Definition of "Schedule 7 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 8 substance" . . . . . .

[Definition of "Schedule 8 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 9 substance" . . . . . .

[Definition of "Schedule 9 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Secretary" . . . . . .

[Definition of "Secretary" deleted by s. 1 (f) of Act No. 20 of 1981.]

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

"this Act" includes any regulation;

"the territory" . . . . . .

[Definition of "the territory" deleted by s. 1 (o) of Act No. 94 of 1991 and by s. 1 of Act No. 49 of 1996.]

"trainee pharmacist" . . . . . .

[Definition of "trainee pharmacist" deleted by s. 1 (o) of Act No. 94 of 1991.]

"unqualified assistant" . . . . . .

[Definition of "unqualified assistant" deleted by s. 1 (g) of Act No. 17 of 1979.]

"veterinarian" means a person registered as such under the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982);

[Definition of "veterinarian" substituted by s. 1 (p) of Act No. 94 of 1991.]

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

[Definition of "veterinary medicine" added by s. 1 (h) of Act No. 17 of 1979.]

"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.

[Definition of "vigilance" inserted by s. 1 (j) of Act No. 14 of 2015.]

(2) Subject to section 15C, a medicine shall, notwithstanding the fact that its components are identical to those of any other medicine as to physical characteristics, quantity and quality, for the purpose of this Act not be regarded as being the same medicine as that other medicine if registration thereof is not applied for by the holder of the certificate of registration issued in respect of that other medicine.

[Sub-s. (2) substituted by s. 1 (i) of Act No. 17 of 1979, by s. 1 (g) of Act No. 20 of 1981 and by s. 1 (j) of Act No. 90 of 1997.]

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

[Sub-s. (3) substituted by s. 1 (j) of Act No. 17 of 1979.]

(4) International tendering for medicines shall be allowed in the prescribed manner and on the prescribed conditions.

[S. 1 substituted by s. 1 (1) of Act No. 65 of 1974. Sub-s (4) added by s. 1 (k) of Act No. 90 of 1997.]

2. Establishment of South African Health Products Regulatory Authority.—(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.

[Sub-s. (1) substituted by s. 2 (b) of Act No. 14 of 2015.]

(2) The Authority is—

(*a*) a juristic person;

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

(*c*) accountable to and reports to the Minister.

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

by this Act.

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

(5) The Authority acts through its Board.

[S. 2 amended by s. 2 (1) of Act No. 65 of 1974, by s. 2 of Act No. 94 of 1991 and by s. 2 of Act No. 90 of 1997, substituted by s. 2 of Act No. 72 of 2008 and amended by s. 2 (a) of Act No. 14 of 2015. Sub-s. (5) added by s. 2 (c) of Act No. 14 of 2015.]

(5) The Authority acts through its Board.

[Sub-s. (5) added by s. 2 (c) of Act No. 14 of 2015.]

2A. Objects of Authority.—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.

[S. 2A inserted by s. 3 of Act No. 14 of 2015.]

2B. Functions of Authority.—(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.

[S. 2B inserted by s. 3 of Act No. 14 of 2015.]

2C. Composition of Board.—(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.

[S. 2C inserted by s. 3 of Act No. 14 of 2015.]

2D. Appointment of members of Board.—(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.

[S. 2D inserted by s. 3 of Act No. 14 of 2015.]

2E. Appointment of chairperson and vice-chairperson of Board.—(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.

[S. 2E inserted by s. 3 of Act No. 14 of 2015.]

2F. Disqualification from membership of Board and vacation of office.—(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.

[S. 2F inserted by s. 3 of Act No. 14 of 2015.]

2G. Meetings of Board.—(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.

[S. 2G inserted by s. 3 of Act No. 14 of 2015.]

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

[S. 2H inserted by s. 3 of Act No. 14 of 2015.]

2I. Dissolution of Board.—(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).

[S. 2I inserted by s. 3 of Act No. 14 of 2015.]

3. Chief Executive Officer and other staff of Authority.—(1) The Board, after consultation with the Minister, must appoint a suitably qualified person as the Chief Executive Officer of the Authority.

[Sub-s. (1) substituted by s. 4 (a) of Act No. 14 of 2015.]

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

(*a*) is an unrehabilitated insolvent;

(*b*) is mentally unfit; or

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

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

(*a*) serious misconduct;

(*b*) permanent incapacity; or

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

(4) The Chief Executive Officer—

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

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

[Para. (b) substituted by s. 4 (b) of Act No. 14 of 2015.]

(*c*) is accountable to and reports to the Board;

[Para. (c) substituted by s. 4 (b) of Act No. 14 of 2015.]

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

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

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

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

(*h*) must compile business and financial plans and reports in terms of the Public Finance Management Act,

1999 (Act No. 1 of 1999).

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

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

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

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

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

(9) The Chief Executive Officer shall, 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.

[S. 3 amended by s. 3 of Act No. 65 of 1974, by s. 1 of Act No. 36 of 1977, by s. 2 of Act No. 17 of 1979, by s. 46 of Act No. 97 of 1986 and by s. 3 of Act No. 94 of 1991, substituted by s. 3 of Act No. 90 of 1997 and by s. 3 of Act No. 72 of 2008. Sub-s. (9) substituted by s. 4 (c) of Act No. 14 of 2015.]

4. . . . . . .

[S. 4 amended by s. 4 (1) of Act No. 65 of 1974 and by s. 4 of Act No. 90 of 1997, substituted by s. 4 of Act No. 72 of 2008 and repealed by s. 5 of Act No. 14 of 2015.]

5. . . . . . .

[S. 5 amended by s. 46 of Act No. 97 of 1986 and repealed by s. 5 of Act No. 72 of 2008.]

6. . . . . . .

[S. 6 amended by s. 5 of Act No. 65 of 1974, by s. 3 of Act No. 17 of 1979, by s. 46 of Act No. 97 of 1986, by s. 4 of Act No. 94 of 1991 and by s. 1 of Act No. 49 of 1996, substituted by s. 5 of Act No. 90 of 1997, amended by s. 2 (a)-(*b*) of Act No. 59 of 2002 and repealed by s. 5 of Act No. 72 of 2008.]

7. . . . . . .

[S. 7 amended by s. 6 of Act No. 65 of 1974 and repealed by s. 5 of Act No. 72 of 2008.]

8. . . . . . .

[S. 8 repealed by s. 5 of Act No. 72 of 2008.]

9. . . . . . .

[S. 9 amended by s. 7 of Act No. 65 of 1974 and by s. 6 of Act No. 90 of 1997 and repealed by s. 5 of Act No. 72 of 2008.]

10. . . . . . .

[S. 10 substituted by s. 8 (1) of Act No. 65 of 1974 (English only), amended by s. 4 of Act No. 17 of 1979 and by s. 46 of Act No. 97 of 1986 and repealed by s. 5 of Act No. 94 of 1991.]

11. . . . . . .

[S. 11 amended by s. 9 of Act No. 65 of 1974, by s. 5 of Act No. 17 of 1979 and by s. 46 of Act No. 97 of 1986 and repealed by s. 6 of Act No. 94 of 1991.]

12. . . . . . .

[S. 12 substituted by s. 10 (1) of Act No. 65 of 1974, amended by s. 7 of Act No. 90 of 1997, substituted by s. 3 of Act No. 59 of 2002 and repealed by s. 5 of Act No. 72 of 2008.]

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

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

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

(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.

[S. 13 amended by s. 11 (1) of Act No. 65 of 1974 (English only) and substituted by s. 2 of Act No. 20 of 1981, by

s. 6 of Act No. 72 of 2008 and by s. 6 of Act No. 14 of 2015.]

14. Prohibition on the sale of medicines, medical devices or IVDs which are subject to registration and are not registered.—(1) Save as provided in this section or sections 21 and 22A, no person shall sell any medicine, medical device or IVD which is subject to registration by virtue of a declaration published in terms of subsection (2) unless it is registered.

(2) (a) The Authority may from time to time determine that a medicine, medical device or IVD, or class or category of medicine, medical device or IVD or part of any class or category of medicine, medical devices or IVDs mentioned in the declaration, shall be subject to registration in terms of this Act.

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

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

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

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

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

[Para. (b) substituted by s. 7 of Act No. 14 of 2015.]

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

(*a*) compounded in the course of carrying on his or her professional activities by a pharmacist, veterinarian or person who is the holder of a licence contemplated in section 22C (1) (a), for a particular patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or

(*b*) compounded by a pharmacist in a quantity not greater than that prescribed by regulation for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian or a practitioner or a nurse or other person registered under the Health Professions Act, 1974, and referred to in section 22A, as the case may be,

if such medicine does not contain any component the sale of which is prohibited by this Act or any component in respect of which an application for registration has been rejected, and is not or has not been advertised: Provided that the active components of such medicine appear in another medicine which has been registered under this Act.

[S. 14 substituted by s. 1 (1) of Act No. 29 of 1968 and by s. 12 (1) of Act No. 65 of 1974, amended by s. 6 of Act No. 17 of 1979, s. 7 (a)-(*c*) of Act No. 94 of 1991, by s. 8 (a)-(*b*) of Act No. 90 of 1997 and substituted by s. 7 of Act No. 72 of 2008.]

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

(*a*) the prescribed particulars;

(*b*) samples of the relevant medicines;

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

(*d*) the prescribed registration fee.

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

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

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

(ii) complies with the prescribed requirements; and

[Sub-para. (ii) amended by s. 8 (a) of Act No. 14 of 2015.]

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

[Sub-para. (iii) substituted by s. 8 (a) of Act No. 14 of 2015.]

(iv) . . . . . .

[Sub-para. (iv) deleted by s. 8 (b) of Act No. 14 of 2015.]

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

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

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

[Para. (c) substituted by s. 8 (c) of Act No. 14 of 2015.]

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

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

(6) Any registration under this section—

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

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

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

(8) If no such representations are lodged by the applicant concerned within a period of 30 days after the receipt by him or her of any notification referred to in subsection (7), or if after consideration of any such representations the Authority is still of the opinion that the condition in question should be imposed, the Authority shall register the medicine, medical device or IVD concerned subject to the said condition.

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

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

[S. 15 amended by s. 2 of Act No. 29 of 1968, substituted by s. 13 of Act No. 65 of 1974, amended by s. 8 of Act No. 94 of 1991 and by s. 9 (a)-(*f*) of Act No. 90 of 1997 and substituted by s. 8 of Act No. 72 of 2008.]

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

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

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

[S. 15A inserted by s. 3 of Act No. 20 of 1981 and substituted by s. 9 of Act No. 72 of 2008.]

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

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

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

[S. 15B inserted by s. 3 of Act No. 20 of 1981 and substituted by s. 10 of Act No. 72 of 2008.]

15C. Measures to ensure supply of more affordable medicines.—The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—

(*a*) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of

the medicine, or with his or her consent;

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

[Para. (b) substituted by s. 11 of Act No. 72 of 2008.]

(*c*) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

[S. 15C inserted by s. 10 of Act No. 90 of 1997.]

16. Cancellation of registration.—(1) If the Authority—

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

[Para. (a) amended by s. 9 of Act No. 14 of 2015.]

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

[Para. (b) amended by s. 9 of Act No. 14 of 2015.]

(*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,

[Para. (c) added by s. 9 of Act No. 14 of 2015.]

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

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

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

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

[S. 16 amended by s. 3 of Act No. 29 of 1968, by s. 14 of Act No. 65 of 1974 (English only) and by s. 4 (b) of Act No. 20 of 1981 and substituted by s. 12 of Act No. 72 of 2008.]

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

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

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

[S. 17 amended by s. 4 of Act No. 29 of 1968, substituted by s. 15 of Act No. 65 of 1974, amended by s. 5 of Act No. 20 of 1981 and substituted by s. 13 of Act No. 72 of 2008.]

18. Labels and advertisements.—(1) No person shall sell any—

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

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

[Sub-s. (1) substituted by s. 10 of Act No. 14 of 2015.]

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

[Sub-s. (2) substituted by s. 10 of Act No. 14 of 2015.]

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

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

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

[S. 18 substituted by s. 16 of Act No. 65 of 1974 and by s. 7 of Act No. 17 of 1979, amended by s. 11 of Act No. 90 of 1997 and substituted by s. 14 of Act No. 72 of 2008.]

18A. Bonusing.—(1) No person shall supply any 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.

[S. 18A inserted by s. 12 of Act No. 90 of 1997 and substituted by s. 15 of Act No. 72 of 2008 and by s. 11 of Act No. 14 of 2015.]

(Date of commencement: 2 May, 2004.)

18B. Sampling of medicines, medical devices or IVDs.—(1) No person shall sample any medicine, medical devices or IVD.

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

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

[S. 18B inserted by s. 12 of Act No. 90 of 1997 and substituted by s. 16 of Act No. 72 of 2008.]

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

[S. 18C inserted by s. 12 of Act No. 90 of 1997, substituted by s. 4 of Act No. 59 of 2002 and by s. 17 of Act No. 72 of 2008.]

19. Prohibition on sale of medicines, medical devices or IVDs which do not comply with prescribed requirements and furnishing of information regarding medicines, medical devices or IVDs to the Authority.—(1) No person shall sell any medicine, medical device or IVD unless it complies with the prescribed requirements.

(2) The Authority may by notice in writing require any person who manufactures or sells 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 medicine, medical device or IVD.

[Sub-s. (2) substituted by s. 12 of Act No. 14 of 2015.]

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

[S. 19 amended by s. 17 of Act No. 65 of 1974 (English only) and substituted by s. 18 of Act No. 72 of 2008.]

20. Publication or distribution of false advertisements concerning medicines, medical devices or IVDs.—(1) No person shall—

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

(*b*) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine, medical device or IVD is other than that stated by the Authority in terms of section 22 (1) (a) (ii) or state or suggest that any 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 section 22 (1) (a) (ii).

[Para. (b) substituted by s. 13 of Act No. 14 of 2015.]

(2) It shall be a sufficient defence in any prosecution for an offence under paragraph (a) of subsection (1) if it is proved to the satisfaction of the court that the accused, not being a person selling the medicine, medical device or IVD to which the false or misleading advertisement which is the subject of the prosecution relates, did not know, and could not reasonably be expected to have known, that the advertisement was in any respect false or misleading.

[S. 20 amended by s. 18 of Act No. 65 of 1974 (English only) and substituted by s. 19 of Act No. 72 of 2008.]

21. Authority may authorize sale of unregistered medicines, medical devices or IVDs for certain purposes.—(1) The Authority may in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine, medical device or IVD which is not registered.

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

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

[S. 21 amended by s. 19 of Act No. 65 of 1974 (English only) and substituted by s. 20 of Act No. 72 of 2008.]

22. Authority to cause certain information to be furnished.—(1) The Chief Executive Officer shall cause, in such manner as he or she considers most suitable—

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

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

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

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

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

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

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

[S. 22 substituted by s. 20 of Act No. 65 of 1974, by s. 8 of Act No. 17 of 1979 amended by s. 6 of Act No. 20 of 1981 and substituted by s. 21 of Act No. 72 of 2008.]

22A. Control of medicines, Scheduled substances, medical devices and IVDs.—(1) Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine, Scheduled substance, medical device or IVD, except in accordance with the prescribed conditions.

[Sub-s. (1) substituted by s. 14 (b) of Act No. 14 of 2015.]

(2) The Minister may, on the recommendation of the Authority, prescribe the Scheduled substances referred to in this section.

[Sub-s. (2) substituted by s. 22 (a) of Act No. 72 of 2008.]

(3) Any Schedule 0 substance may be sold in an open shop.

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

(*a*) by any person other than—

(i) a pharmacist, or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist;

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

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

(*aa*) prescribe such substance;

(*bb*) compound and dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);

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

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

(*aa*) prescribe only the Scheduled substances identified in the Schedule for that purpose;

(*bb*) compound and dispense the Scheduled substances referred to in item (aa) only if he or she is the holder of a licence contemplated in section 22C (1) (a);

(*b*) to any person apparently under the age of 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C (1) (a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 12 years;

[Para. (b) substituted by s. 22 (b) of Act No. 72 of 2008.]

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

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

(*a*) a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;

(*b*) a pharmacist or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;

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

(*d*) a medical practitioner or dentist, who may—

(i) prescribe such substance;

(ii) compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);

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

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

(i) prescribe only the Scheduled substances identified in the Schedule for that purpose;

(ii) compound and dispense the Scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 22C (1) (a).

(6) Any sale under subsection (5) shall only take place on condition that—

(*a*) all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner;

(*b*) the authorised prescriber who has given verbal instructions to a pharmacist to dispense a prescription shall within seven days after giving such instructions furnish such pharmacist with a prescription confirming such instructions;

(*c*) in the case of verbal instructions the treatment period shall not exceed seven days;

(*d*) if a prescription is not presented for dispensing within 30 days of issue it shall not be dispensed;

(*e*) in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C (1) (a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 12 years;

[Para. (e) substituted by s. 22 (c) of Act No. 72 of 2008.]

(*f*) in the case of a Schedule 2, Schedule 3 or Schedule 4 substance, such sale may be repeated if the person who issued the prescription has indicated thereon the number of times it may be dispensed, but not for longer than six months;

(*g*) in the case of a Schedule 5 substance, such sale shall not be repeated for longer than six months, and then only if the authorised prescriber has indicated on the prescription the number of times and the intervals at which it may be dispensed;

(*h*) where a Schedule 5 substance is used for—

(i) its anxiolytic, anti-depressant or tranquillising properties it shall not be prescribed for longer than six months unless the authorised prescriber has consulted a registered psychiatrist, or, in the case of a psychiatrist, another psychiatrist before issuing a new prescription;

(ii) its analgesic properties it shall not be prescribed for longer than six months unless the authorised prescriber has consulted another medical practitioner, before issuing a new

prescription;

(*i*) in the case of a Schedule 6 substance, it shall not be repeated without a new prescription being issued;

(*j*) in an emergency in which the health or life of a patient is at stake, a pharmacist engaged in wholesale practice may, on receipt of a telephonic or telefaxed or other electronic request, supply a Schedule 6 substance to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, without a written order: Provided that—

(i) it shall be the responsibility of such pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person to ensure that such pharmacist receives a written order within seven days;

(ii) the Schedule 6 substance shall be supplied in the smallest unit sales pack available;

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

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

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

(*m*) a pharmacist may sell a greater or a lesser quantity of a Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance than the quantity prescribed or ordered, according to the therapeutic pack in the original container of such substance as supplied to him or her, but the quantity so sold shall not exceed or be less than, 25 percent of the quantity specified in the prescription or order in question;

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

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

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

[Para. (p) substituted by s. 5 (a) of Act No. 59 of 2002.]

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

(*r*) any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance for the treatment of any animal may be supplied by any person practising a para-veterinary profession within the meaning of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982), upon a written prescription issued by a veterinarian or on the verbal instructions of a veterinarian.

(7) (*a*) No person, other than a pharmacist, pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, shall sell or export a Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, unless a permit, issued in accordance with the prescribed conditions has, subject to paragraph (b), been obtained from the Director-General for such purpose.

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

(8) Subject to subsection (9), a Schedule 8 substance shall not be acquired by any person other than the Director-General for the purpose of providing a medical practitioner therewith, on the prescribed conditions, for the treatment of a particular patient of that medical practitioner upon such conditions as the Director-General, on the recommendation of the council, may determine.

[Sub-s. (8) substituted by s. 5 (b) of Act No. 59 of 2002.]

(9) (*a*) No person shall—

(i) acquire, use, possess, manufacture or supply any Schedule 7 or Schedule 8 substance, or

manufacture any specified Schedule 5 or Schedule 6 substance unless he or she has been issued with a permit by the Director-General for such acquisition, use, possession, manufacture or supply: Provided that the Director-General may, subject to such conditions as he or she may determine, acquire or authorise the use of any Schedule 7 or Schedule 8 substance in order to provide a medical practitioner, analyst, researcher or veterinarian therewith on the prescribed conditions for the treatment or prevention of a medical condition in a particular patient, or for the purposes of education, analysis or research;

[Sub-para. (i) substituted by s. 5 (c) of Act No. 59 of 2002.]

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

(*b*) Notwithstanding paragraph (a), the Director-General may at any time revoke any permit issued in terms of that paragraph if any condition on which the permit was issued is not being complied with.

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

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

(11) (*a*) No person shall import or export any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance or other substance or medicine prescribed for that purpose unless a permit has been issued to him or her by the Director-General in the prescribed manner and subject to such conditions as may be determined by the Director-General.

[Para. (a) substituted by s. 5 (d) of Act No. 59 of 2002.]

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

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

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

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

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

(iv) the Director-General is of the opinion that such substance or medicine, of an acceptable quality, is already available in the Republic; or

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

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

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

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

(i) any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance;

[Sub-para. (i) substituted by s. 5 (e) of Act No. 59 of 2002.]

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

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

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

[Para. (b) substituted by s. 5 (f) of Act No. 59 of 2002.]

(*c*) Notwithstanding paragraph (b), no such importation or exportation shall take place unless authorised by the Director-General.

[Para. (c) substituted by s. 5 (g) of Act No. 59 of 2002.]

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

(*a*) to the applicant's furnishing the Chief Executive Officer annually with the prescribed information;

[Para. (a) substituted by s. 22 (d) of Act No. 72 of 2008.]

(*b*) to the requirement that there shall be no deviation from the particulars reflected on the permit: Provided that if the quantity of such substance or medicine to be imported is less than that provided for in the permit, the Director-General shall be informed in writing thereof within 10 days after the importation of such substance or medicine; and

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

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

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

[Para. (a) substituted by s. 5 (h) of Act No. 59 of 2002.]

(*b*) no nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe a medicine or Scheduled substance unless he or she has been authorised to do so by his or her professional council concerned.

(15) Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the South African Pharmacy Council as referred to in section 2 of the Pharmacy Act, 1974 (Act No. 53 of 1974), issue a permit to any person or organisation performing a health service, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and such permit shall be subject to such conditions as the Director-General may determine.

[Sub-s. (15) substituted by s. 22 (e) of Act No. 72 of 2008.]

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

(*a*) any person may possess a Schedule 0, Schedule 1 or Schedule 2 substance for medicinal purposes;

(*b*) any person may possess a Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance if he or she is in possession of a prescription issued by an authorised prescriber;

[Para. (b) substituted by s. 5 (i) of Act No. 59 of 2002.]

(*c*) any medicine or scheduled substance may be possessed by a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, or under the Veterinary and Para-Veterinary Professions Act, 1982, for the purposes of administering it in accordance with his or her scope of practice;

(*d*) any medicine or scheduled substance may be possessed for sale by a pharmacist, a person licenced to own a pharmacy in terms of the Pharmacy Act, 1974, or a person who is the holder of a licence as contemplated in section 22C.

(17) For the purposes of this section—

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

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

[S. 22A inserted by s. 21 of Act No. 65 of 1974, amended by s. 9 of Act No. 17 of 1979 and by s. 7 of Act No. 71 of 1991, substituted, and subsequently re-substituted (after amendment), by s. 9 of Act No. 94 of 1991 and by s. 13 of Act No. 90 of 1997 and amended by s. 14 (a) of Act No. 14 of 2015.]

22B. Publication of information relating to medicines, Scheduled substances, medical devices or IVDs.—(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 medicine, Scheduled substance, medical device or IVD.

[Sub-s. (1) substituted by s. 15 (b) of Act No. 14 of 2015.]

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

[S. 22B inserted by s. 10 of Act No. 94 of 1991, substituted by s. 23 of Act No. 72 of 2008 and amended by s. 15 (a) of Act No. 14 of 2015.]

22C. Licensing.—(1) Subject to the provisions of this section—

(*a*) the Director-General may on application in the prescribed manner and on payment of the prescribed

fee issue to a medical practitioner, 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;

[Para. (a) substituted by s. 16 (a) of Act No. 14 of 2015.]

(*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 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 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.

[Sub-s (1) amended by s. 6 (a) of Act No. 59 of 2002 and substituted by s. 24 (a) of Act No. 72 of 2008. Para. (b) substituted by s. 16 (a) of Act No. 14 of 2015.]

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

[Sub-s. (2) substituted by s. 6 (b) of Act No. 59 of 2002 and by s. 24 (b) of Act No. 72 of 2008.]

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

[Sub-s. (3) substituted by s. 24 (c) of Act No. 72 of 2008.]

(4) When the Director-General or the Authority, as the case may be, grants or refuses an application for a licence—

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

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

[Sub-s. (4) amended by s. 24 (d) of Act No. 72 of 2008.]

(5) No person shall compound or dispense a medicine unless he or she is authorised thereto in terms of the Pharmacy Act, 1974, is a veterinarian or is the holder of a licence as contemplated in subsection (1) (a).

[Sub-s. (5) substituted by s. 6 (c) of Act No. 59 of 2002.]

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

[Sub-s. (6) substituted by s. 6 (d) of Act No. 59 of 2002, by s. 24 (e) of Act No. 72 of 2008 and by s. 16 (b) of Act No. 14 of 2015.]

(7) Subsections (5) and (6) shall come into operation twelve months from the date of commencement of this section.

[S. 22C inserted by s. 14 of Act No. 90 of 1997. Sub-s. (7) substituted by s. 6 (e) of Act No. 59 of 2002.]

22D. Period of validity and renewal of licence.—A licence issued under section 22C shall be valid for the prescribed period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Director-General or the Authority, as the case may be, may allow and on payment of the prescribed fee.

[S. 22D inserted by s. 14 of Act No. 90 of 1997 and by s. 25 of Act No. 72 of 2008.]

22E. Suspension and cancellation of licence.—(1) If the holder of a licence under section 22C—

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

[Para. (a) substituted by s. 26 (a) of Act No. 72 of 2008.]

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

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

(*d*) has, in the case of a licence issued in terms of section 22C (1) (a), at any time been convicted of an offence which is of such a nature that, in the opinion of the Director-General, it renders him or her unsuitable to compound or dispense medicines,

the Director-General or the Authority, as the case may be, may by way of a notice in writing call upon him or her to show cause within the period specified in the notice, which period shall not be less than 20 days as from the date of the notice, why the licence in question should not be suspended or revoked.

[Para. (d) amended by s. 26 (b) of Act No. 72 of 2008.]

(2) The Director-General or the Authority, as the case may be, may after considering the reasons furnished in terms of subsection (1)—

(*a*) suspend the licence in question for such period the Director-General or the Authority may determine; or

(*b*) revoke the licence in question.

[Sub-s. (2) substituted by s. 26 (c) of Act No. 72 of 2008.]

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

[S. 22E inserted by s. 14 of Act No. 90 of 1997.]

22F. Generic substitution.—(1) Subject to subsections (2), (3) and (4), a pharmacist or a person licensed in terms of section 22C (1) (a) shall—

(*a*) inform all members of the public who visit the pharmacy or any other place where dispensing takes place, as the case may be, with a prescription for dispensing, of the benefits of the substitution for a branded medicine by an interchangeable multi-source medicine, and shall, in the case of a substitution, take reasonable steps to inform the person who prescribed the medicine of such substitution; and

[Para. (a) substituted by s. 7 (b) of Act No. 59 of 2002.]

(*b*) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.

[Sub-s. (1) amended by s. 7 (a) of Act No. 59 of 2002.]

(2) If a pharmacist is forbidden as contemplated in subsection (1) (b), that fact shall be noted by the pharmacist on the prescription.

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.

(4) A pharmacist shall not sell an interchangeable multi-source medicine—

(*a*) if the person prescribing the medicine has written in his or her own hand on the prescription the words "no substitution" next to the item prescribed;

(*b*) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or

(*c*) where the product has been declared not substitutable by the Authority.

[S. 22F inserted by s. 14 of Act No. 90 of 1997. Para. (c) substituted by s. 27 of Act No. 72 of 2008.]

22G. Pricing committee.—(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.

[Sub-s. (1) substituted by s. 8 (a) of Act No. 59 of 2002.]

(2) The Minister may, on the recommendation of the pricing committee, make regulations—

(*a*) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;

(*b*) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C (1) (a);

(*c*) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule O medicines.

[Para. (c) added by s. 8 (b) of Act No. 59 of 2002.]

(3) (*a*) The transparent pricing system contemplated in subsection (2) (a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.

(*b*) No pharmacist or person licensed in terms of section 22C (1) (a) or a wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).

[Para. (b) substituted by s. 8 (c) of Act No. 59 of 2002.]

(*c*) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2) (b).

(4) To the members of the pricing committee who are not in the full-time employment of the State may be

paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

[S. 22G inserted by s. 14 of Act No. 90 of 1997.]

22H. Purchase and sale of medicines, medical devices, IVDs and Scheduled substances by wholesalers.—(1) (*a*) No wholesaler shall purchase 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 medicines, medical devices or IVDs only into the retail sector; and

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

[Sub-s. (1) substituted by s. 28 of Act No. 72 of 2008 and by s. 17 (b) of Act No. 14 of 2015.]

(2) Subsection (1) shall not be construed as preventing the return of medicines, medical devices or IVDs for credit purposes only, to the manufacturer or wholesaler from which those medicines, medical devices or IVDs were initially obtained.

[Sub-s. (2) substituted by s. 28 of Act No. 72 of 2008 and by s. 17 (b) of Act No. 14 of 2015.]

(3) Any wholesaler may in the prescribed manner and on the prescribed conditions be exempted by the Director-General from the provisions of subsection (1).

[S. 22H inserted by s. 14 of Act No. 90 of 1997 and amended by s. 17 (a) of Act No. 14 of 2015.]

23. Disposal of undesirable medicines, medical devices or IVDs.—(1) If the Authority is of the opinion that it is not in the public interest that any medicine, medical device or IVD shall be made available to the public, it may—

(*a*) by notice in writing transmitted by registered post to any person direct that person; or

(*b*) by notice in the *Gazette* direct any person,

to return any quantity of such medicine, medical device or IVD which he or she has in his or her possession to the manufacturer thereof or (in the case of any imported medicine, medical device or IVD) to the importer concerned or to deliver or send it to any other person designated by the Authority.

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

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

[Sub-s. (3) amended by s. 22 of Act No. 65 of 1974 (English only) and substituted by s. 29 of Act No. 72 of 2008.]

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

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

[S. 24 amended by s. 23 of Act No. 65 of 1974, substituted by s. 11 of Act No. 94 of 1991 and by s. 15 of Act No. 90 of 1997, amended by s. 9 (a)-(*g*) of Act No. 59 of 2002 and substituted by s. 30 of Act No. 72 of 2008.]

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

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

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

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

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

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

hear the appeal.

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

[S. 24A inserted by s. 31 of Act No. 72 of 2008.]

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

[S. 25 substituted by s. 32 of Act No. 88 of 1996, by s. 10 of Act No. 59 of 2002 and by s. 32 of Act No. 72 of 2008.]

26. Inspectors.—(1) The Chief Executive Officer may authorize such persons as inspectors as he or she may consider necessary for the proper enforcement of this Act.

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

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

[S. 26 substituted by s. 24 (1) of Act No. 65 of 1974, amended by s. 1 of Act No. 19 of 1976 and by s. 10 of Act No. 17 of 1979 and substituted by s. 33 of Act No. 72 of 2008.]

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

[S. 27 substituted by s. 25 (1) of Act No. 65 of 1974, by s. 11 of Act No. 17 of 1979 and by s. 34 of Act No. 72 of 2008.]

28. Powers of inspectors.—(1) An inspector may, at all reasonable times—

(*a*) enter upon—

(i) any place or premises from which a person, authorized under this Act to compound or dispense medicines or Scheduled substances, dispenses or handles 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

[Sub-para. (i) substituted by s. 35 (a) of Act No. 72 of 2008 and by s. 18 (a) of Act No. 14 of 2015.]

(ii) any place, premises, vessel or aircraft if he or she suspects on reasonable grounds that an offence in terms of this Act has been or is being committed thereon or therein or that an attempt has been made or is being made to commit such an offence thereon or therein; or

(iii) any private dwelling, with the consent of the occupier or under the authority of a warrant issued in terms of subsection (5) or without a warrant in terms of subsection (6);

(*b*) inspect any 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);

[Para. (b) substituted by s. 35 (b) of Act No. 72 of 2008 and by s. 18 (b) of Act No. 14 of 2015.]

(*c*) seize any such 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;

[Para. (c) substituted by s. 35 (b) of Act No. 72 of 2008 and by s. 18 (b) of Act No. 14 of 2015.]

(*d*) take so many samples of any such 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.

[Sub-s. (1) amended by s. 26 (a) of Act No. 65 of 1974 and by s. 16 of Act No. 90 of 1997 and substituted by s. 11 (a) of Act No. 59 of 2002. Para. (d) inserted by s. 35 (c) of Act No. 72 of 2008 and substituted by s. 18 (b) of Act No. 14 of 2015.]

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

(i) be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such medicine, 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;

[Sub-para. (i) substituted by s. 18 (c) of Act No. 14 of 2015.]

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

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

[Sub-para. (iii) substituted by s. 18 (d) of Act No. 14 of 2015.]

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

[Sub-s. (2) amended by s. 26 (a) of Act No. 65 of 1974, substituted by s. 12 (a) of Act No. 17 of 1979 and by s. 35 (d) of Act No. 72 of 2008. Para. (b) substituted by s. 18 (e) of Act No. 14 of 2015.]

(3) The analyst, pharmacologist, 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.

[Sub-s. (3) substituted by s. 12 (b) of Act No. 17 of 1979 and by s. 18 (f) of Act No. 14 of 2015.]

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

[Sub-s. (4) substituted by s. 26 (b) of Act No. 65 of 1974, by s. 35 (e) of Act No. 72 of 2008 and by s. 18 (f) of Act No. 14 of 2015.]

(5) Where on application to a magistrate in appears to such magistrate from information on oath that there are reasonable grounds to believe that—

(*a*) the conditions for entry described in subsection (1) (a) exist in relation to a private dwelling:

(*b*) entry to that private dwelling is necessary for any purpose relating to the administration or enforcement of this Act; and

(*c*) entry to the private dwelling has been refused or that entry thereto will be refused,

a magistrate may issue a warrant authorizing the inspector named therein to enter that private dwelling subject to such conditions as may be specified in the warrant.

[Sub-s. (5) added by s. 11 (b) of Act No. 59 of 2002.]

(6) If an inspector believes on reasonable grounds that—

(*a*) a warrant would be issued to him or her under subsection (5) if he or she applies for such a warrant; and

(*b*) a delay in obtaining such warrant would defeat the object of the entry, search and seizure,

he or she may without a warrant enter and search any premises for any medicines, scheduled substance, book, record or document relevant to the administration or enforcement of this Act and seize or take samples as contemplated in subsection (1) (c).

[Sub-s. (6) added by s. 11 (b) of Act No. 59 of 2002.]

29. Offences.—Any person who—

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

[Para. (a) substituted by s. 17 (a) of Act No. 90 of 1997.]

(*b*) contravenes or fails to comply with the provisions of section 14 (1), 18, 18A or 18B; or

[Para. (b) substituted by s. 17 (a) of Act No. 90 of 1997.]

(*c*) contravenes the provisions of section 19 (1) or fails to comply with a notice issued under section 19 (2); or

[Para. (c) substituted by s. 17 (a) of Act No. 90 of 1997.]

(*d*) contravenes the provisions of section 20 (1); or

[Para. (d) substituted by s. 17 (a) of Act No. 90 of 1997.]

(*e*) contravenes or fails to comply with any condition imposed under section 15 (6)

[Para. (e) substituted by s. 17 (a) of Act No. 90 of 1997 and by s. 36 (a) of Act No. 72 of 2008.]

(*f*) fails to comply with any direction given under section 23 or contravenes the provisions of section 23 (3); or

[Para. (f) substituted by s. 17 (a) of Act No. 90 of 1997.]

(*g*) with fraudulent intent tampers with any sample taken in terms of this Act; or

(*h*) makes any false or misleading statement in connection with any medicine, Scheduled substance,

medical device or IVD—

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

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

[Para. (h) substituted by s. 27 (a) of Act No. 65 of 1974 and amended by s. 36 (b) of Act No. 72 of 2008 and by s. 19 (a) of Act No. 14 of 2015.]

(*i*) sells any 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

[Para. (i) substituted by s. 27 (b) of Act No. 65 of 1974, by s. 36 (c) of Act No. 72 of 2008 and by s. 19 (b) of Act No. 14 of 2015.]

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

(*k*) contravenes any provision of section 22A, 22C (5) and (6), 22F, 22G or 22H or contravenes or fails to comply with any condition imposed thereunder;

[Para. (k) added by s. 27 (d) of Act No. 65 of 1974 and substituted by s. 17 (b) of Act No. 90 of 1997.]

(*l*) contravenes or fails to comply with the provisions of section 34;

[Para. (l) added by s. 12 of Act No. 94 of 1991.]

(*m*) manufactures, sells or uses a veterinary medicine in contravention of a prohibition referred to in section 36A, or contravenes, or fails to comply with, a condition imposed in terms of the said section,

[Para. (m) added by s. 12 of Act No. 94 of 1991.]

shall be guilty of an offence.

30. Penalties.—(1) Any person who is convicted of an offence referred to in section 29 shall be liable to a fine, or to imprisonment for a period not exceeding 10 years.

[Sub-s. (1) substituted by s. 13 of Act No. 94 of 1991 and by s. 18 (a) of Act No. 90 of 1997.]

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

[Sub-s. (2) amended by s. 28 (a) of Act No. 65 of 1974 and substituted by s. 37 (a) of Act No. 72 of 2008 and by s. 20 (a) of Act No. 14 of 2015.]

(3) Any 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.

[Sub-s. (3) substituted by s. 28 (b) of Act No. 65 of 1974, by s. 37 (b) of Act No. 72 of 2008 and by s. 20 (b) of Act No. 14 of 2015.]

(4) Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty provided for in this section.

[Sub-s. (4) added by s. 18 (b) of Act No. 90 of 1997.]

31. Procedure and evidence.—(1) In any criminal proceedings under this Act—

(*a*) any quantity of a 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;

[Para. (a) amended by s. 29 of Act No. 65 of 1974 and substituted by s. 38 (a) of Act No. 72 of 2008 and by s. 21 (a) of Act No. 14 of 2015.]

(*b*) . . . . . .

[Para. (b) deleted by s. 19 (a) of Act No. 90 of 1997.]

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

(*d*) any statement or entry contained in any book, record or document kept by any owner of a 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.

[Para. (d) amended by s. 29 of Act No. 65 of 1974 and substituted by s. 38 (b) of Act No. 72 of 2008 and by s. 21 (b) of Act No. 14 of 2015.]

(2) . . . . . .

[Sub-s. (2) substituted by s. 13 of Act No. 17 of 1979 and deleted by s. 19 (b) of Act No. 90 of 1997.]

(3) The court in which any such certificate is adduced in evidence may in its discretion cause the person who signed such certificate to be summoned to give oral evidence in the proceedings in question or may cause written interrogatories to be submitted to him for reply, and such interrogatories and any reply thereto, purporting to be a reply from such person, shall be admissible in evidence in such proceedings.

32. . . . . . .

[S. 32 amended by s. 30 of Act No. 65 of 1974 (English only) and repealed by s. 20 of Act No. 90 of 1997.]

33. Act or omission by manager, agent or employee.—(1) Whenever any manager, agent or employee of any person (hereinafter called the employer) does or omits to do any act which it would be an offence under this Act for the employer to do or omit to do, then unless it is proved that—

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

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

(*c*) it was not under any condition or in any circumstances within the scope of the authority or in the course of the employment of the manager, agent or employee to do or to omit to do acts, whether lawful or unlawful, of the character of the act or omission charged,

the employer shall be presumed himself to have done or omitted to do that act and shall be liable to be convicted and sentenced in respect thereof; and the fact that he issued instructions forbidding any act or omission of the kind in question shall not, of itself, be accepted as sufficient proof that he took all reasonable steps to prevent the act or omission.

(2) Whenever any manager, agent or employee of any such employer does or omits to do an act which it would be an offence under this Act for the employer to do or omit to do, he shall be liable to be convicted and sentenced in respect thereof as if he were the employer.

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

33A. Funds of Authority.—(1) The funds of the Authority shall consist of—

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

(*b*) fees raised and interest on overdue fees;

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

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

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

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

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

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

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

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

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

[S. 33A inserted by s. 21 of Act No. 90 of 1997 and substituted by s. 39 of Act No. 72 of 2008.]

34. Preservation of secrecy.—No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director-General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain or for the benefit of his employer.

[S. 34 substituted by s. 14 of Act No. 94 of 1991.]

34A. Delegation of powers.—(1) The Minister may in writing authorise the Director-General or any officer of the Department of Health to exercise any of the powers conferred upon the Minister by this Act other than the powers referred to in sections 3, 24 (1) and 35, or to exercise or perform any of the duties or functions conferred or imposed on the Minister in terms of this Act.

[Sub-s. (1) substituted by s. 22 (a) of Act No. 90 of 1997.]

(2) The Director-General may in writing authorize any officer of the Department of Health to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function, excluding any power, duty or function referred to in subsection (1), conferred or imposed on the Director-General by or in terms of this Act.

[Sub-s. (2) amended by s. 22 (b) of Act No. 90 of 1997.]

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

[S. 34A inserted by s. 2 of Act No. 19 of 1976, substituted by s. 15 of Act No. 94 of 1991. Sub-s. (3) added by s. 40 of Act No. 72 of 2008.]

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

(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;

[Para. (i) substituted by s. 22 (a) of Act No. 14 of 2015.]

(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);

[Para. (ii) substituted by s. 22 (a) of Act No. 14 of 2015.]

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

[Para. (iii) substituted by s. 22 (a) of Act No. 14 of 2015.]

(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;

[Para. (iv) substituted by s. 22 (a) of Act No. 14 of 2015.]

(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;

[Para. (v) substituted by s. 22 (a) of Act No. 14 of 2015.]

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

[Para. (vi) substituted by s. 22 (a) of Act No. 14 of 2015.]

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

[Para. (vii) substituted by s. 22 (a) of Act No. 14 of 2015.]

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

[Para. (viii) substituted by s. 22 (a) of Act No. 14 of 2015.]

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

[Para. (ix) substituted by s. 22 (a) of Act No. 14 of 2015.]

(x) prescribing the particulars which shall appear in any advertisement relating to any medicine, 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;

[Para. (x) substituted by s. 22 (a) of Act No. 14 of 2015.]

(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;

[Para. (xi) substituted by s. 22 (a) of Act No. 14 of 2015.]

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

[Para. (xii) substituted by s. 41 (b) of Act No. 72 of 2008.]

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

[Para. (xiii) substituted by s. 41 (c) of Act No. 72 of 2008.]

(xiv) prescribing the particulars which shall appear on a prescription or an order for a medicine or a Scheduled substance, the number of issues of a medicine or a Scheduled substance that may be made on any such specified prescription or order, the manner in which any such prescription or order shall be issued and the period for which any such prescription or order shall be retained;

(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;

[Para. (xv) substituted by s. 22 (b) of Act No. 14 of 2015.]

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

(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;

[Para. (xvii) substituted by s. 22 (c) of Act No. 14 of 2015.]

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

[Para. (xviii) substituted by s. 22 (c) of Act No. 14 of 2015.]

(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;

[Para. (xix) substituted by s. 22 (c) of Act No. 14 of 2015.]

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

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

(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;

[Para. (xxii) substituted by s. 22 (d) of Act No. 14 of 2015.]

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

[Para. (xxiii) substituted by s. 22 (d) of Act No. 14 of 2015.]

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

[Para. (xxiv) substituted by s. 12 (a) of Act No. 59 of 2002 and by s. 22 (d) of Act No. 14 of 2015.]

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

(xxvi) prescribing the methods to be employed and the form of the certificates to be issued in connection with the testing, examination or analysis of samples taken under this Act;

(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;

[Para. (xxvii) substituted by s. 12 (b) of Act No. 59 of 2002 and by s. 22 (e) of Act No. 14 of 2015.]

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

[Para. (xxviii) substituted by s. 22 (e) of Act No. 14 of 2015.]

(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;

[Para. (xxix) substituted by s. 22 (e) of Act No. 14 of 2015.]

(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;

[Para. (xxx) substituted by s. 22 (e) of Act No. 14 of 2015.]

(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 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 medicine, medical device or IVD and the date on which such annual fee shall be paid;

[Para. (xxxi) substituted by s. 41 (d) of Act No. 72 of 2008 and by s. 22 (e) of Act No. 14 of 2015.]

(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, medical devices or IVDs for the purpose of registration, the evaluation of technical amendments and changes to the particulars contained in registers and the testing for batch release of biological medicines;

[Para. (xxxii) substituted by s. 22 (e) of Act No. 14 of 2015.]

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

[Para. (xxxiii) substituted by s. 41 (e) of Act No. 72 of 2008.]

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

[Para. (xxxiv) substituted by s. 22 (f) of Act No. 14 of 2015.]

(xxxv) relating to the repackaging of medicines in patient-ready packs;

(xxxvi) relating to the safety, quality and efficacy of any interchangeable multi-source medicine;

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

[Para. (xxxvii) substituted by s. 41 (f) of Act No. 72 of 2008.]

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

[Para. (xxxviii) substituted by s. 22 (g) of Act No. 14 of 2015.]

(xxxix) relating to the control and conduct of clinical trials;

(xl) relating to 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);

[Para. (xl) inserted by s. 41 (g) of Act No. 72 of 2008 and substituted by s. 22 (h) of Act No. 14 of 2015.]

(xli) relating to the control of medicines, Scheduled substances, medical devices and IVDs in general;

[Para. (xli) inserted by s. 41 (g) of Act No. 72 of 2008 and substituted by s. 22 (h) of Act No. 14 of 2015.]

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

[Para. (xlii) inserted by s. 41 (g) of Act No. 72 of 2008 and substituted by s. 22 (h) of Act No. 14 of 2015.]

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

[Para. (xliii) inserted by s. 41 (g) of Act No. 72 of 2008.]

(xliv) with regard to any matter which in terms of this Act shall or may be prescribed; and

[Para. (xliv), previously para. (xl) renumbered by s. 41 (g) of Act No. 72 of 2008.]

(xlv) generally for the efficient carrying out of the objects and purposes of this Act, and the generality of this provision shall not be limited by the preceding paragraphs of this subsection.

[Sub-s. (1) amended by s. 41 (a) of Act No. 72 of 2008. Para. (xlv), previously para. (xli) renumbered by s. 41 (g) of Act No. 72 of 2008]

(2) The Minister shall, not less than three months before any regulation is made under subsection (1), cause the text of such regulation to be published in the *Gazette*, together with a notice declaring his or her intention to make that regulation and inviting interested persons to furnish him or her with any comments thereon or any representations they may wish to make in regard thereto.

(3) The provisions of subsection (2) shall not apply in respect of—

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

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

[Para. (b) substituted by s. 41 (h) of Act No. 72 of 2008.]

(4) A regulation under subsection (1) (xxxi) and (xxxii) shall be made only in consultation with the Minister of Finance.

(5) Regulations made under subsection (1) (xi) may prescribe that any 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.

[Sub-s. (5) substituted by s. 41 (i) of Act No. 72 of 2008 and by s. 22 (i) of Act No. 14 of 2015.]

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

[Sub-s. (6) substituted by s. 41 (j) of Act No. 72 of 2008 and by s. 22 (i) of Act No. 14 of 2015.]

(7) (*a*) Regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith of a fine, or imprisonment for a period not exceeding 10 years.

(*b*) Notwithstanding anything to the contrary in any law contained a magistrate's court shall be competent to impose any penalty provided for in paragraph (a).

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

[S. 35 amended by s. 5 of Act No. 29 of 1968, by s. 1 of Act No. 88 of 1970 and by s. 7 of Act No. 95 of 1971, substituted by s. 31 (1) of Act No. 65 of 1974, amended by s. 3 of Act No. 19 of 1976, by s. 14 of Act No. 17 of 1979, by s. 7 of Act No. 20 of 1981, by s. 7 of Act No. 71 of 1991 and by s. 16 of Act No. 94 of 1991 and substituted by s. 23 of Act No. 90 of 1997. Sub-s. (8) substituted by s. 41 (k) of Act No. 72 of 2008]

36. Exclusion of any medicine, Scheduled substance, medical device or IVD from operation of Act.—(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 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 medicine or Scheduled substance from the operation of sections 18A and 22G shall be effected by the Minister on the recommendation of the Pricing Committee.

[S. 36 amended by s. 32 of Act No. 65 of 1974 (English only) and substituted by s. 42 of Act No. 72 of 2008 and by s. 23 of Act No. 14 of 2015.]

36A. Minister may prohibit the manufacture, sale or use of certain veterinary medicines.—Notwithstanding anything to the contrary in this Act or in any other law contained, the Minister may by notice in the *Gazette* for any reason other than the safety, quality or therapeutic efficacy of a veterinary medicine—

(*a*) prohibit the manufacture, sale or use of any veterinary medicine containing a substance mentioned in the notice; or

(*b*) prohibit such manufacture, sale or use, except in accordance with such conditions as may be specified in the notice,

and may in like manner repeal or amend such notice.

[S. 36A inserted by s. 17 of Act No. 94 of 1991.]

37. . . . . . .

[S. 37 substituted by s. 33 of Act No. 65 of 1974 and by s. 18 of Act No. 94 of 1991 and repealed by s. 24 of Act No. 90 of 1997.]

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

[S. 37A inserted by s. 34 of Act No. 65 of 1974, repealed, and subsequently re-inserted (after amendment), by s. 19 of Act No. 94 of 1991, substituted by s. 25 of Act No. 90 of 1997 and by s. 43 of Act No. 72 of 2008.]

38. Operation of Act in relation to other laws.—The provisions of this Act shall be in addition to and not in substitution for any other law which is not in conflict with or inconsistent with this Act.

39. State bound.—This Act binds the State.

[S. 39 repealed by s. 20 of Act No. 94 of 1991 and inserted by s. 26 of Act No. 90 of 1997.]

(Date of commencement: 1 July, 2005.)

40. Short title.—This Act shall be called the Medicines and Related Substances Act, 1965.

[S. 40 substituted by s. 35 of Act No. 65 of 1974 and by s. 28 of Act No. 90 of 1997.]