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DEPARTMENT OF HEALTH

NO. 859

25 AUGUST 2017

MEDICINES AND RELATED SUBSTANCES ACT, 1965**GENERAL REGULATIONS**

The Minister of Health, in consultation with the Authority, has in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), made the Regulations in the Schedule.

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DEFINITIONS

1. In these Regulations any word or expression to which a meaning has been assigned in the Act shall have the meaning so assigned and, unless the context otherwise indicates—

“**adverse drug reaction**” means a noxious and unintended response to a medicine;

“**adverse event**” is any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment;

“**as determined by the Authority**” means as determined by the South African Health Products Regulatory Authority (SAHPRA in guidelines as published from time to time;

“**authorised prescriber**” means any person authorised by the Act to prescribe any medicine;

“**batch**” or “**lot**” in relation to a medicine means a defined quantity of a medicine manufactured in a single manufacturing cycle and which has homogeneous properties;

“**batch number**” or “**lot number**” means a unique number or combination of numbers or ciphers allocated to a lot or a batch by the manufacturer;

“**bioequivalence**” means the absence of a statistically significant difference in bioavailability between two pharmaceutically equivalent products under similar conditions in an appropriately designed study;

“**bonded warehouse**” means a customs and excise warehouse licensed in terms of section 19 of the Customs and Excise Act, 1964 (Act No. 91 of 1964);

“**Chief Executive Officer**” means the Chief Executive Officer of the Authority as appointed in terms of section 3 of the Act;

“**clinical trial**” means an investigation in respect of a medicine for use in humans or animals that involves human participants or animals and that is intended to—

- (a) discover or verify the clinical, pharmacological or pharmacodynamic effects of the medicine;
- (b) identify any adverse events;
- (c) study the absorption, distribution, metabolism and excretion of the medicine; or
- (d) ascertain its safety or efficacy;

“**complementary medicine**” means any substance or mixture of substances that—

- (a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the Authority;
- (b) is used or purporting to be suitable for use or manufactured or sold for use—
 - (i) in maintaining, complementing or assisting the physical or mental state; or
 - (ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal; and
- (c) is used—
 - (i) as a health supplement; or
 - (ii) in accordance with those disciplines as determined by the Authority;

“compound” means to prepare, mix, combine, package and label a medicine—

- (a) by a pharmacist, pharmacist intern or pharmacist’s assistant practising in accordance with the Pharmacy Act for—
 - (i) an individual patient; or
 - (ii) an animal as a result of a prescription issued by a veterinarian practising in accordance with the Veterinary and Para-Veterinary Professions Act, 1982 (Act No.19 of 1982); or
- (b) for dispensing as a result of a prescription for a patient by a person licensed in terms of section 22C(1)(a) of the Act and practising in accordance with the relevant scope of practice;

“counterfeit medicine” means a medicine in respect of which a false representation has been made about its contents, identity or source by any means including its labelling and packaging;

“dispense”—

- (a) in the case of a pharmacist, means dispense as defined in the Regulations Relating to the Practice of Pharmacy made in terms of the Pharmacy Act; or
- (b) in the case of a medical practitioner, dentist, practitioner, veterinarian, nurse or any authorised prescriber to dispense medicines, means—
 - (i) the interpretation and evaluation of a prescription;
 - (ii) the selection, reconstitution, dilution, labelling, recording and supply of the medicine in an appropriate container; or
 - (iii) the provision of information and instructions to ensure safe and effective use of a medicine by a patient;

“dosage form” means the pharmaceutical form in which the active ingredients and excipients, and physical formulation of a medicine is presented;

“expiry date” means the date up to which a medicine will retain the strength and other properties stated on the label which strength and other properties can change after the lapse of time and after which date the medicine shall not be sold to the public or used;

“health care provider” means a health care provider as defined in section 1 of the National Health Act, 2003 (Act No. 61 of 2003);

“health supplement” means any substance, extract or mixture of substances as determined by the Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying any physical or mental state by—

- (a) complementing health;
- (b) supplementing the diet; or
- (c) a nutritional effect,

and excludes injectable preparations, medicines or substances listed as Schedule 1 or higher in the Act;

“holder of a certificate of registration” means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medicine, including quality and safety and compliance with conditions of registration;

“identification number” means the number drawn from a—

- (a) birth certificate, passport, valid driver's licence;
- (b) South African identification document; or
- (c) any other relevant document issued by the Department of Home Affairs;

“manufacture” means all operations including purchasing of material, processing, production, packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls;

“manufacturer” means a person manufacturing a medicine and includes a manufacturing pharmacy;

“minimum legibility” means a printing in 6-point Helvetica, typeface in black ink on white cartridge paper or the equivalent thereof;

“misbranded” means labelling which is false, misleading, inaccurate or fails to provide information as required;

“parallel importation” means the importation into the Republic of a medicine protected under patent or registered in the Republic that has been put onto the market outside the Republic by or with the consent of such patent holder;

“patient information leaflet” means the information pertaining to a medicine as provided for in regulation 12, written in a manner which is easily understandable by the patient;

“person” means a natural or a juristic person;

“Pharmacy Act” means the Pharmacy Act, 1974 (Act No. 53 of 1974);

“professional information” means the information about a medicine as provided for in regulation 11;

“proprietary name”, “brand name” or “trade name” means the name which is unique to a particular medicine and by which the medicine is generally identified and which in the case of a registered medicine is the name approved in terms of section 15(5) of the Act;

“responsible pharmacist” means a responsible pharmacist as defined in section 1 of the Pharmacy Act;

“Site Master File” means a document prepared by the manufacturer containing specific and factual good manufacturing practice information about the production or control of pharmaceutical manufacturing operations carried out at a named site and any closely integrated operations at adjacent and nearby buildings;

“sugar” means any of a class of natural, water-soluble crystalline carbohydrates, of relatively low molecular weight, and typically having a sweet taste depending on the polymeric composition, and includes related alcohols such as sorbitol, mannitol, and xylitol;

“sweetener” means any additive or excipient other than sugar which is used or intended to be used to impart a sweet taste to medicines;

“the Act” means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended; and

“wholesaler” including a wholesale pharmacy means a person who holds, stores, delivers or purchases medicines or Scheduled substances from a manufacturer and sells them in terms of section 22H of the Act.

REQUIREMENTS FOR THERAPEUTIC EQUIVALENCE

2. (1) A medicine is considered therapeutically equivalent to another medicine if both medicines—

(a) are—

(i) pharmaceutically equivalent, in that they contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered by the same route; or

(ii) pharmaceutical alternatives, in that they contain the same active moiety but differ either in chemical form of that moiety or in the dosage form or strength; and

(b) after administration in the same molar dose, their effects with respect to both efficacy and safety are essentially the same.

(2) Therapeutic equivalence is determined from comparative bioavailability, pharmacodynamic, clinical or in vitro studies which meet the requirements and accepted criteria for bioequivalence as determined by the Authority.

CONDITIONS FOR COMPOUNDING MEDICINE

3. (1) A pharmacist or other person licensed in terms of section 22C(1)(a) of the Act to compound a medicine for sale in terms of section 14(4) of the Act, shall only compound a quantity that is intended to be used by a patient for not more than 30 consecutive days from the date of compounding: Provided that the date of compounding and the statement “Use within 30 days” are clearly indicated on the label.

(2) Any medicine compounded in terms of section 14(4) may not be advertised or displayed for sale.

(3) No medicine may be compounded by a pharmacist or other person licensed in terms of section 22C(1)(a) of the Act to compound a medicine for sale—

(a) to circumvent the provisions of section 14 of the Act;

(b) which has been declared undesirable in terms of section 23 of the Act;

(c) for the purpose of growth promotion or performance enhancement;

(d) for the purpose of administering to food-producing animals if—

- (i) Maximum Residue Limits (MRL); and
- (ii) appropriate withdrawal times,
have not been established;
- (e) for use by a patient not under the professional care of an authorised prescriber or pharmacist;
- (f) for purpose of export; or
- (g) unless the compounding thereof is performed in accordance with good practice as determined by the Authority.

THE MANNER AND CONDITIONS FOR ALLOWING INTERNATIONAL TENDERING

4. (1) The State may tender for a medicine internationally if such a medicine—
- (a) can be obtained at a lower price outside of the Republic; or
 - (b) is essential for national health.
- (2) A medicine cannot be procured by international tender unless such medicine is registered in terms of the Act.

IMPORTATION OF MEDICINES CONTEMPLATED IN SECTION 15C

5. (1) A medicine referred to in section 15C(b) of the Act may be sold if—
- (a) the medicine is being sold outside the Republic with the consent of the holder of the patent of such medicine;
 - (b) the medicine is imported from a person licensed by a regulatory authority recognised by the Authority;
 - (c) the person desiring to import such medicine is in possession of a permit issued by the Authority; and
 - (d) the medicine is registered in terms of the Act, if such a medicine is so declared.
- (2) A person desiring to import a medicine referred to in subregulation (1) shall submit to the Authority—
- (a) a duly completed application on a form obtainable from the Authority;
 - (b) a certified copy of his or her identity document or in the case of a juristic person, a certificate of registration as such or other material proof of incorporation or existence as a juristic person in the Republic;
 - (c) a certified copy of registration in terms of the Pharmacy Act, where applicable;
 - (d) a certified copy of a licence in respect of premises in terms of—

- (i) section 19 of Customs and Excise Act, 1964 (Act No. 91 of 1964); and
 - (ii) section 22 of the Pharmacy Act;
- (e) documentary proof—
- (i) that the medicine is under patent in the Republic;
 - (ii) that the medicine is registered in its country of export by a regulatory authority recognised by the Authority;
 - (iii) regarding the lowest price at which the medicine is sold in the Republic;
 - (iv) regarding the price at which the medicine will be sold in the Republic;
 - (v) that he, she or it can comply with good manufacturing and distribution practices as determined by the Authority; and
- (f) an undertaking that he, she or it will ensure the continued safety, efficacy and quality of the medicine.
- (3) The Authority—
- (a) may approve the application referred to in subregulation (2) with or without conditions;
 - (b) shall, if the application is approved, issue the applicant with a permit, which shall be valid for a period of two years; and
 - (c) may cancel the permit if the holder thereof fails to comply with the conditions of the permit or on any other good cause shown.
- (4) The permit issued in terms of subregulation (3) may only be transferred with the approval of the Authority.
- (5) A person issued with a permit in terms of subregulation (3) shall apply to the Authority for the registration of the medicine specified in the permit by submitting to the Chief Executive Officer—
- (a) a certified copy of that permit;
 - (b) an application form obtainable from the Authority completed by the applicant; and
 - (c) the applicable application fee.
- (6) The Authority—
- (a) must, if satisfied that the application referred to in subregulation (5) complies with the requirements of the Act and these regulations regarding the safety, efficacy and quality of the medicine, and that its registration is in the public interest, approve the application with or without conditions; and

- (b) may issue the person referred to in subregulation (5) with a certificate of registration in respect of such medicine under the name approved by the Authority.

- (7) A person importing a medicine in terms of this regulation shall in writing inform—
 - (a) the Authority of any change of facts in relation to the application for a permit issued in terms of subregulation (3) or conditions under which such permit was issued;
 - (b) the Authority of any amendments to the application for the registration of medicines or the conditions for the registration of such medicine; and
 - (c) the holder of a certificate of registration in the Republic of the importation of the medicine in terms of this regulation.

- (8) A medicine registered in terms of this regulation may only be sold to the State or a person authorised to sell medicines in terms of the Act or any other legislation.

IMPORTATION OF MEDICINES INTO REPUBLIC

- 6.** (1) No person shall import any medicine or scheduled substance, including medicines imported in terms of section 15C of the Act, into the Republic except through one of the following ports of entry:
- (a) Cape Town International Airport or harbour;
 - (b) Port Elizabeth International Airport or harbour;
 - (c) King Shaka International Airport or Durban harbour; and
 - (d) O.R. Tambo International Airport.
- (2) A person shall only import a medicine or scheduled substance if such person—
- (a) is licensed in terms of the Act to import medicines; and
 - (b) in the case of unregistered medicines, is authorised by the Authority to import such unregistered medicines.
- (3) An application for authorisation referred to in subregulation (2)(b) shall contain at least the following information:
- (a) Name and address (both physical and postal) of the applicant;
 - (b) designation of the person representing the applicant;
 - (c) contact details of the applicant including the—
 - (i) telephone number; and
 - (ii) facsimile number or email address;

- (d) the name of the medicine being imported;
- (e) the quantity of medicine being imported;
- (f) the batch number of the medicine being imported; and
- (g) the expiry date of the medicine.

TRANSMISSION OF MEDICINES THROUGH REPUBLIC

7. (1) Subject to the provisions of the Act, medicines and scheduled substances that are transmitted through the Republic shall—

- (a) while in the Republic, be stored in a bonded warehouse which is licensed in terms of section 22C by the Authority to import or export medicines or Scheduled substances; and
- (b) not be manipulated while in the bonded warehouse unless such authority has been issued by the Authority.

(2) A bonded warehouse referred to in subregulation (1) shall comply with good distribution practice and licence conditions as determined by the Authority.

PERSONAL MEDICINAL USE BY PERSONS ENTERING REPUBLIC

8. (1) Notwithstanding regulation 6, any person entering the Republic may be in possession, for personal medicinal use, of—

- (a) a quantity of a Schedule 3, 4 or 5 substance, which shall not exceed the quantity required for use for a period of six months; or
- (b) a quantity of a Schedule 6 substance, which shall not exceed the quantity required for use for a period of 30 days.

(2) A person referred to in subregulation (1) shall have—

- (a) the original prescription for such a Scheduled substance;
- (b) a certified copy of such prescription; or
- (c) a certificate or letter issued by the person who prescribed or dispensed such Scheduled substance certifying that the Scheduled substance and the quantity concerned was prescribed for the person entering the Republic, and including the name, physical and email address of the person who prescribed or dispensed the prescription concerned.

CATEGORIES AND CLASSIFICATION OF MEDICINES

9. (1) Medicines shall be classified into categories as follows:
- (a) Category A = Medicines which are intended for use in humans and which are, without manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine;
 - (b) Category B = Medicines intended for use in humans and animals which cannot normally be administered without further manipulation;
 - (c) Category C = Medicines intended for veterinary use which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine; and
 - (d) Category D = Complementary medicines intended for use in humans and animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine.
- (2) Medicines in Category D shall be classified into the following sub-categories:
- (a) discipline-specific medicines with such disciplines as determined by the Authority; and
 - (b) health supplements.
- (3) Medicines in Categories A and D (human complementary medicine) are subdivided into classes as per Annexure 1.
- (4) Medicines in categories C and D (veterinary complementary medicines) are subdivided into classes as per Annexure 2.

LABELLING OF MEDICINES INTENDED FOR HUMAN USE

10. (1) Subject to subregulations (4) and (5), the immediate container of every medicine in which a medicine intended for administration to or use by humans is sold shall have a label attached to it on which the following particulars shall appear in clearly legible indelible letters in English and at least one other official language—
- (a) in the case of a medicine containing any substance listed in any Schedule made in terms of the Act, the letter "S" followed by the number of the relevant Schedule, in a prominent typeface and size and surrounded by a square border, immediately preceding the proprietary name of such medicine;
 - (b) the proprietary name of the medicine;
 - (c) the—

- (i) registration number of the medicine allocated in terms of section 15(5) of the Act; or
 - (ii) application number allocated by the Authority followed by the expression "Act 101/1965";
- (d) the dosage form of the medicine;
- (e) the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit, or per suitable mass or volume or unit, ranked according to the active ingredients with the highest schedule, in lettering which has minimum legibility: Provided that labelling of medicines in solutions for injections must identify the active ingredient in terms of the active component per unit volume of solution;
- (f) the name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative;
- (g) the approved name of any anti-oxidant contained in the medicine;
- (h) in the case of a medicine—
 - (i) for oral or parenteral administration which contains sugar, the statement: "contains sugar" and the name and quantity of the sugar must be stated or which does not contain sugar, the statement: "sugar free";
 - (ii) for oral or parenteral administration the quantity of ethyl alcohol contained in the medicine, expressed as a percentage of the total volume of the medicine, if such quantity exceeds two per cent by volume; and
 - (iii) for oral administration the name and quantity of sweetener other than sugar contained in the medicine and the statement: "contains sweetener".
- (i) the content of the medicine package expressed in the appropriate unit or volume of the medicine;
- (j) approved indications where practical, for use of the medicine;
- (k) the recommended dosage of the medicine, where practical;
- (l) where applicable, the instruction "Shake the bottle before use";
- (m) in the case of a medicine intended for injection by a particular route of administration only, that route of administration by means of suitable words or abbreviations;
- (n) the lot number of the medicine;
- (o) the expiry date of the medicine in a font size that makes it clearly visible;
- (p) a barcode suitable for the identification and tracking of medication: Provided that where such barcode appears on the outer label it may be excluded on the immediate container label;
- (q) the name of the holder of certificate of registration of the said medicine;

- (r) the requirements regarding the manner in which the medicine shall be stored with specific reference to the applicable storage temperature, humidity and light exposure and other precautions required for the preservation of the medicine;
- (s) where applicable, the statement: "For external use only";
- (t) the warning: "Keep out of reach of children";
- (u) in the case of a medicine which contains aspirin or paracetamol, the warning: "Do not use continuously for more than 10 days without consulting your doctor";
- (v) in the case of a medicine for oral administration which contains fluorides, the warning: "Contains fluoride";
- (w) in the case of a medicine for oral administration which contains an antihistamine, the warning: "This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressants";
- (x) in the case of eye drops or artificial tear solutions in respect of which evidence concerning the self-sterilising ability of the medicine has not been approved by the Authority, the warning: "Do not use more than 30 days after opening";
- (y) any specified warning to be given on the label of the medicine as a condition of registration thereof as may have been determined in terms of section 15(6) of the Act;
- (z) in the case of a medicine that contains tartrazine, the warning: "Contains TARTRAZINE";
- (aa) the category of medicine immediately preceding the registration or application number;
- (bb) the class of the medicine in terms of Annexure 1; and
- (cc) in the case of complementary medicine—
 - (i) the words "Complementary Medicine";
 - (ii) a statement identifying the discipline or the wording "Health Supplement", as the case may be;
 - (iii) which is not registered by the Authority, the following disclaimer: "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use."; and
 - (iv) containing at least 5 percent of modified organisms the following warning "contains genetically modified organisms".

(2) In addition to the requirement of subregulation (1), the following information may be included on the label:

- (a) The name and address of the manufacturer of the medicine;
- (b) the date of manufacture of the medicine; or

- (c) the scheduling status and registration number allocated by another national medicines regulatory authority of a country as determined by the Authority: Provided that this information is surrounded by a square border including the name of the reference country.

(3) If the medicine package bears both, an immediate container label and an outer label, the requirements of subregulation (1) shall apply to the outer label: Provided that it shall be sufficient to contain on the immediate container label—

- (a) in the case of Category A medicines—
- (i) intended for administration by injection and having a total volume not exceeding 5 ml, the particulars referred to in subregulation (1)(b),(e), (m), (n) and (o);
 - (ii) in the form of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the particulars referred to in subregulation (1)(b), (c), (e), (f), (n), (o), (q) and (y);
 - (iii) in the form of liquid, solution or suspension having a total volume of more than 1 ml, but not exceeding 15 ml, the particulars referred to in subregulation (1)(b), (c), (d), (e), (n), (o), (q), (x) and (y);
 - (iv) in the form of a liquid, solution or suspension having a total volume not exceeding 1 ml, the particulars referred to in subregulation (1)(b) and (n); and
 - (v) packed in blister or similar packaging, the particulars referred to in subregulation (1)(b), (n), (o), and (q), repeated as frequently as is practicable; and
- (b) in the case of Category D medicines—
- (i) intended for administration by injection and having a total volume not exceeding 5 ml, the particulars referred to in subregulation (1)(b), (m), (n), (o) and (cc)(i);
 - (ii) in the form of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the particulars referred to in subregulation (1)(b), (c), (f), (n), (o), (q), (y) and (cc)(i);
 - (iii) in the form of liquid, solution or suspension having a total volume of more than 1 ml, but not exceeding 15 ml, the particulars referred to in subregulation (1)(b), (c), (d), (n), (o), (q), (x), (y) and (cc)(i);
 - (iv) in the form of a liquid, solution or suspension having a total volume not exceeding 1 ml, the particulars referred to in subregulation (1)(b), (n) and (cc)(i); and
 - (v) packed in blister or similar packaging, the particulars referred to in subregulation (1)(b), (n), (o), (q) and (cc)(i), repeated as frequently as is practicable.

(4) The Authority may authorise the inclusion on the label of a medicine of any special information that is not required by this regulation to be so included.

(5) The requirements of subregulation (1) shall not apply to—

- (a) any medicine sold in accordance with section 14(4) of the Act;
- (b) any medicine sold by a person licensed to dispense in terms of section 22C(1)(a) of the Act or a pharmacist, pharmacist intern or pharmacist's assistant in the course of his or her professional activities for the treatment of a particular patient; or
- (c) any medicine sold by a pharmacist, a person authorised to compound and dispense, or in a hospital pharmacy in accordance with a prescription issued by a medical practitioner or dentist for the treatment of a particular patient.

(6) For any medicine sold in terms of subregulation (5), such medicine shall be sold in a package to which is attached a label containing the following information:

- (a) the proprietary name, approved name, or the name of each active ingredient of the medicine, where applicable, or constituent medicine;
- (b) the name of the person for whose treatment such medicine is sold;
- (c) the directions in regard to the manner in which such medicine should be used;
- (d) the name and business address of the person authorised to sell such a medicine;
- (e) date of dispensing;
- (f) reference number; and
- (g) a statement identifying the discipline of the medicine, if falling under Category D.

PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

11. (1) Subject to subregulation (4), professional information shall be made available—
- (a) for each medicine—
 - (i) in hard copy either separately or as an integral part of the package; or
 - (ii) electronically: Provided that the manner in which the professional information may be accessed is stated on the patient information leaflet as contemplated in regulation 12(2)(p);
 - (b) in the English language;
 - (c) in type having a minimum legibility; and
 - (d) under the headings and shall contain the particulars specified in subregulation (2).

(2) Subject to subregulations (3) and (4), the professional information referred to in subregulation (1) shall contain the following particulars:

- (a) Scheduling status of the medicine assigned by the Authority;
- (b) proprietary name and dosage form;
- (c) composition, including—
 - (i) the approved name of each active ingredient and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine;
 - (ii) the approved name of all excipients included in the formulation;
 - (iii) the approved name and quantity of any bactericidal or bacteriostatic agent included in the medicine as a preservative, expressed as a percentage;
 - (iv) the quantity of ethyl alcohol included in a preparation for oral or parenteral administration, if such quantity exceeds two per cent by volume;
 - (v) the words "contains TARTRAZINE" should the medicine contain such ingredient;
 - (vi) in the case of a medicine, for oral or parenteral administration, which contains sugar, the statement: "contains sugar" and the name and quantity of the sugar must be stated or which does not contain sugar, the warning: "sugar free"; and
 - (vii) in the case of a medicine, for oral administration, which contains sweetener, the name and quantity of sweetener and the statement: "contains sweetener";
- (d) the category and class, including the number and the description as stated in regulation 9;
- (e) pharmacological action and, where applicable, under a sub-heading: Pharmacokinetic properties, pharmacodynamic properties; summary of pre-clinical or clinical studies;
- (f) indications;
- (g) contraindications;
- (h) warnings and special precautions;
- (i) interactions;
- (j) human reproduction;
- (k) dosage and directions for use;
- (l) side effects;
- (m) known symptoms of over-dosage and particulars of its treatments;
- (n) identification;
- (o) presentation;
- (p) storage instructions that are practically formulated and which indicate storage temperatures, humidity and exposure to light;

- (q) registration number which corresponds to—
 - (i) the number allocated in terms of section 15(5) of the Act; or
 - (ii) in the case of a medicine the registration of which has been applied for, the reference number allocated to such application, followed by the expression "Act 101/1965";
- (r) name and business address of the holder of the certificate of registration, or in case of a parallel imported medicine, the name and business address of the holder of the parallel importation permit;
- (s) date of publication of the professional information which is the date of the most recent amendment to the professional information as approved by the Authority, as well as the date of registration: Provided that—
 - (i) if the Authority decides that there is no applicable information to be furnished under a particular heading, such heading may be omitted with the approval of the Authority;
 - (ii) the Authority may on application authorise the deviation from the format and content of the professional information prescribed as a condition of registration of a medicine;
 - (iii) the Authority may on application authorise the inclusion of any specified information not required by this regulation to be so included; and
 - (iv) the Authority may on application determine under a particular heading the information to be furnished in respect of an interchangeable multisource medicine; and
- (t) in the case of a complementary medicine—
 - (i) the words "Complementary Medicine";
 - (ii) a statement identifying the discipline or the wording "Health Supplement", as the case may be;
 - (iii) which is not registered by the Authority, the following disclaimer:

"This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use."; and
 - (iv) containing at least 5 percent of genetically modified organisms the following warning: "contains genetically modified organisms".
- (3) The Authority may determine additional professional information to be provided.
- (4) The requirements of subregulations (1) and (2) shall not apply to—
 - (a) any medicine sold in accordance with the provisions of section 14(4) of the Act;
 - (b) any medicine compounded or sold by a pharmacist or any other person who is licensed to compound and dispense medicines in the course of his or her professional activities for the treatment of a particular patient; and

- (c) any medicine sold by a pharmacist in accordance with a prescription issued by a medical practitioner, dentist or practitioner for the treatment of a particular patient.

(5) Nothing contained in subregulations (4) shall be construed as prohibiting the inclusion of professional information with any medicine.

(6) The Authority may withdraw any indication for a medicine if it is of the opinion that the risk benefit profile for such indication is not in the public interest.

(7) In addition to the requirement of subregulation (2), the following information may be included:

- (a) The name and address of the manufacturer of the medicine;
- (b) the date of manufacture of the medicine; or
- (c) the scheduling status and registration number allocated by another national medicines regulatory authority of a country as determined by the Authority: Provided that this information is surrounded by a square border including the name of the reference country.

PATIENT INFORMATION LEAFLET

12. (1) Each medicine shall be accompanied by a patient information leaflet—

- (a) attached to the immediate container;
- (b) included as part of the immediate container or outer package; or
- (c) inserted into the outer package.

(2) The patient information leaflet shall contain the following information with regard to the medicine in at least English and one other official language—

- (a) scheduling status;
- (b) proprietary name and dosage form;
- (c) the composition of the medicine in terms of information contemplated in regulation 11(2)(c);
- (d) the approved indications and use;
- (e) instructions before taking the medicine, which shall include—
 - (i) contra-indications;
 - (ii) precautions;
 - (iii) warnings;
 - (iv) interactions; and

- (v) the following general statement:
"Always tell your health care provider if you are taking any other medicine. If you are pregnant or breast feeding your baby please consult your health care provider for advice before taking this medicine.";
- (f) instructions on how to take the medicine, including the following statements:
"Do not share medicines prescribed for you with any other person."
"In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre";
- (g) side effects, including the following general statement:
"Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice";
- (h) storage and disposal information, including the following general statement:
"store all medicines out of reach of children.";
- (i) presentation, which includes the number, volume or mass per package unit and a description of the packaging material;
- (j) identification and description of the medicine;
- (k) the—
- (i) registration number of the medicine allocated in terms of section 15(5) of the Act; or
- (ii) application number allocated by the Authority followed by the expression "Act 101/1965";
- (l) the name, business address and telephone number of—
- (i) the holder of the certificate of registration; or
- (ii) the applicant in terms of section 14(3) of the Act;
- (m) date of publication of the patient information leaflet which is the date of the most recent amendment to the patient information leaflet as approved by the Authority, as well as the date of registration of the medicine;
- (n) in the case of a complementary medicine—
- (i) the words "Complementary Medicine";
- (ii) a statement identifying the discipline or the wording "Health Supplement", as the case may be;
- (iii) which is not registered by the Authority, the following disclaimer:
"This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use."; and
- (iv) containing at least 5 percent of genetically modified organisms, the identification of the affected ingredient(s) and the following warning "contains genetically modified organisms";

- (o) in the case of a medicine—
 - (i) for oral or parenteral administration, which contains sugar, the statement: "contains sugar" and the name and quantity of the sugar must be stated or which does not contain sugar, the statement: "sugar free";
 - (ii) for oral or parenteral administration, the quantity of ethyl alcohol contained in the medicine, expressed as a percentage of the total volume of the medicine, if such quantity exceeds two per cent by volume; and
 - (iii) for oral administration, the name and quantity of sweetener other than sugar contained in the medicine and the statement: "contains sweetener"; and
- (p) the manner in which the corresponding professional information as per regulation 11 may be obtained.

(3) Information contemplated in subregulation (2) may also be provided in electronic format accessible in any of the other official languages and in any other format to enable its accessibility for persons living with disabilities.

(4) The Authority may determine additional requirements for inclusion in any patient information leaflet.

(5) The Authority may authorise a deviation from subregulation (1).

(6) The Authority may, on application, in respect of an interchangeable multisource medicine determine additional information to be furnished under a particular heading.

(7) The requirements of subregulation (1) shall not apply to any medicine sold in accordance with section 14(4) of the Act.

(8) In addition to the requirement of sub regulation (2), the following information may be included:

- (a) The name and address of the manufacturer of the medicine;
- (b) the date of manufacture of the medicine; or
- (c) the scheduling status and registration number allocated by another national medicines regulator of a country as determined by the Authority: Provided that this information is surrounded by a square border including the name of the reference country.

LABELLING FOR VETERINARY MEDICINES

13. (1) Subject to subregulations (2), (3) and (4), the immediate container of every package in which a veterinary medicine is sold shall have a label attached to it on which the following particulars pertaining to the contents of such package shall appear in clearly legible, indelible lettering in at least English or one official language:

- (a) The words "Veterinary Medicine";
- (b) in the case of a medicine containing any substance listed in any Schedule made in terms of the Act, the letter "S" followed by the number of the relevant Schedule, in a prominent typeface and size and surrounded by a square border, immediately preceding the proprietary name of such medicine;
- (c) the proprietary name of such medicine;
- (d) the registration number allocated to such medicine under section 15(5) of the Act or, in the case of a medicine in respect of which an application for registration has been submitted in accordance with section 14(3), the reference number allocated to such application by the Authority, followed by the words "(Act 101/1965)";
- (e) the dosage form of the medicine;
- (f) the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit in lettering which shall not be less than—
 - (i) in the case of a medicine containing only one active ingredient, one half the size of the largest lettering which is used for the said proprietary name;
 - (ii) in the case of a medicine which contains more than one but less than six active ingredients, one-quarter the size of the largest lettering which is used for the said proprietary name; and
 - (iii) in the case of a medicine containing six and more active ingredients, the minimum type size permitted by this regulation: Provided that such lettering shall have a minimum legibility;
- (g) the name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative;
- (h) the content of the medicine package expressed in the appropriate unit or volume of the medicine;
 - (i) where practicable, the indications for use of the medicine;
 - (j) where practicable, the recommended dosage of the medicine;
 - (k) where applicable, the instruction "Shake the bottle before use";
- (l) in the case of a medicine intended for injection by a particular route of administration only, that route of administration by means of suitable words or abbreviations;
- (m) in the case of a medicine listed in any Schedule to the Act, the letter 'S' followed by the number of the relevant Schedule, in a prominent typeface and size and

surrounded by a square border, immediately preceding the proprietary name of such medicine;

- (n) the lot number of the medicine;
- (o) the expiry date of the medicine;
- (p) the name of the holder of certificate of registration of the said medicine;
- (q) the requirements regarding the manner in which the medicine shall be stored with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;
- (r) where applicable, the statement: "For external use only";
- (s) the warning: "Keep out of reach of children and uninformed persons";
- (t) in the case of any medicine intended to be used in food producing animals and involving the possibility of the ingredients of such medicine or metabolites thereof being present in the eggs, milk or tissue of such animals, a warning regarding the withdrawal period of such medicine;
- (u) any specified warning which has to be included on the label of a particular medicine as a condition of registration of that medicine in terms of the provisions of section 15(6) of the Act;
- (v) the category of medicine;
- (w) the class of the medicine in terms of Annexure 2; and
- (x) in the case of a complementary medicine—
 - (i) a statement identifying the discipline of the medicine where relevant; and
 - (ii) if the medicine has not received registration with the Authority the following disclaimer: "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use."

(2) If the medicine package bears both an immediate container label and an outer label, the requirements of subregulation (1) shall apply to the outer label: Provided that it shall be sufficient to contain on the immediate container label—

- (a) in the case of medicines intended for administration by injection and having a total volume not exceeding 5 ml, the particulars referred to in subregulation (1)(a), (b), (e), (k), (l) (m), (n) and (w);
- (b) in the case of an ointment, cream, gel or powder having a net mass not exceeding 10 grams, the particulars referred to in subregulation (1)(a), (b), (c), (e), (m), (n), (o) and (w);
- (c) in the case of a liquid, solution or suspension having a total volume more than 1 ml but not exceeding 15 ml, the particulars referred to in subregulation (1)(a), (b), (c), (d), (e), (f), (m), (n), (o) and (w);
- (d) in the case of a liquid, solution or suspension having a total volume not exceeding 1 ml, the particulars referred to in subregulation (1)(a), (b), (o) and (w); and

- (e) in the case of a medicine packed in blister or similar packaging, the particulars referred to in subregulation (1)(a), (b), (m), (n), (o) and (w), repeated as frequently as is practicable.

(3) The Authority may, on application to it by an applicant, authorise the inclusion on the label of a medicine of any specified information, which is not required by this regulation to be so included.

(4) The requirements of subregulation (1) shall not apply to a medicine excluded there from by the Minister in terms of section 36 of the Act or to—

- (a) any medicine sold in accordance with the provisions of section 14(4) of the Act for the treatment of a specific animal;
- (b) any medicine sold by a veterinarian or pharmacist in the course of his or her professional activities for the treatment of a particular animal; or
- (c) any medicine sold by a pharmacist in accordance with a prescription issued by a veterinarian for treatment of a particular animal:

Provided that such medicine shall be sold in a package to which is attached a label containing the following information:

- (i) The name of the medicine or the name of each active ingredient or constituent medicine;
- (ii) the name of the person to whom such medicine has been sold and a description, as accurate as possible, of the animals for which the treatment is intended;
- (iii) the directions for the use of such medicine;
- (iv) the name and address of the veterinarian or pharmacist who has sold such medicine;
- (v) the reference number allocated to the sale of the medicine as referred to in regulation 11(1)(f); and where applicable, the warning, referred to in subregulation (1)(s), regarding the withdrawal period of such medicine;
- (vi) date of dispensing; and
- (vii) a statement identifying the discipline of the medicine, if falling in Category D.

PROFESSIONAL INFORMATION FOR VETERINARY MEDICINES

14. (1) Subject to subregulation (2), professional information shall be made available for each veterinary medicine, in at least English or one official language and in type having a minimum legibility, under the headings and in the format specified in this regulation, and which shall contain the following particulars:

- (a) The proprietary name;

- (b) scheduling status;
 - (c) dosage form;
 - (d) composition, using generic or approved names;
 - (e) class of the medicine in terms of Annexure 2;
 - (f) pharmacological action;
 - (g) pharmacokinetic properties and pharmacodynamic properties;
 - (h) contra-indications;
 - (i) warnings or withdrawal period in the case of food producing animals;
 - (j) side effects and special precautions;
 - (k) known signs of overdose and particulars of its treatment;
 - (l) quantity and strength of active ingredients per dosage unit;
 - (m) storage instructions;
 - (n) registration number;
 - (o) name and business address of holder of certificate of registration;
 - (p) any other information as the Authority may from time to time determine; and
 - (q) in the case of a complementary medicine—
 - (i) a statement identifying the discipline of the medicine where relevant; and
 - (ii) if the medicine has not received registration with the Authority the disclaimer "This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use."
- (2) The Authority may, upon application, authorise a deviation from subregulation (1).

BATCH RELEASE FOR BIOLOGICAL MEDICINES

15. (1) The Authority may, with regard to the registration of biological medicines in terms of section 15(6) of the Act, require that the number of samples of every batch, together with one copy of the protocol of testing of the bulk batch and filling batch and one copy of the certificate of release issued by the competent Authority in the country in which the product was manufactured, be submitted to the Authority as a batch release condition and the holder of the certificate of registration must pay the prescribed batch release fee.

(2) The Authority may, with regard to the registration of biological medicines in terms of section 15(6) of the Act, require that at least the number of samples of every batch, together with one copy of the protocol of testing of the bulk batch and filling batch of the biological medicine manufactured in the Republic be submitted to the National Control Laboratory of the Authority as a batch release condition and the holder of the certificate of registration must pay the prescribed batch release fee.

(3) The Authority may, with regard to the sale of unregistered biological medicines as per the provisions of section 21 of the Act, request a batch release of the medicine as per the requirements of subregulation 1 and 2.

APPLICATION FOR THE REGISTRATION OF A MEDICINE

16. (1) Any person residing in the Republic may make an application for the registration of a medicine on an application form obtainable from the office of the Chief Executive Officer.

(2) The application referred to subregulation (1) must include the particulars of the person with appropriate knowledge of all aspects of the medicine who shall be responsible for communication with the Authority.

(3) The application contemplated in subregulation (1) shall be accompanied by—

- (a) a screening form which is obtainable from the Chief Executive Officer which has been completed by the applicant;
- (b) a proposed label for use on the medicine;
- (c) where applicable, a copy of the manufacturing licence together with the current Good Manufacturing Practice certificate from the regulatory authority of the country where the medicine is manufactured;
- (d) in the case of specified Schedule 5, Schedule 6, Schedule 7 and Schedule 8 substances, a certified copy of a permit to manufacture such substances;
- (e) all available data on the safety, efficacy and quality of the medicine, as may be determined by the Authority;
- (f) proof of the existence of a manufacturing site, which may include a Site Master File;
- (g) any other information as may be required by the Authority; and
- (h) the applicable application fee.

(4) The information referred to in subregulation (3) shall be submitted in English.

(5) The application Form referred to in subregulation (1) shall contain at least the following information:

- (a) particulars of the applicant and the prospective holder of certificate of registration, including—
 - (i) name;
 - (ii) business address;
 - (iii) postal address;

- (iv) telephone number;
 - (v) fax number, if applicable;
 - (vi) e-mail address, if applicable; and
 - (vii) contact details of the person referred to in subregulation (2) in the case of a juristic person; and
- (b) particulars of a medicine, including—
- (i) proposed proprietary name;
 - (ii) dosage form;
 - (iii) strength per dosage unit;
 - (iv) route of administration;
 - (v) the country where the medicine is manufactured;
 - (vi) registration status outside the Republic;
 - (vii) category, class and a statement identifying the discipline if falling under Category D;
 - (viii) the name of the manufacturer(s);
 - (ix) the name of any site where any bioequivalence data was generated; and
 - (x) approved name of each active pharmaceutical ingredient.

(6) A medicine, in respect of which an application for registration is made, must comply with the technical requirements as determined by the Authority.

(7) An application shall be made in respect of each individual dosage form and strength of a medicine.

(8) In the case where a medicine in respect of which an application for registration is made, is or was registered with any regulatory body outside the Republic, the following information in respect of such medicine shall accompany the application:

- (a) a copy of the certificate of registration;
- (b) professional information relating to the medicine;
- (c) conditions of such registration; and
- (d) any other information as may be required by Authority.

(9) The provisions of this regulation shall, with the necessary changes, apply to the application for the registration of veterinary medicines.

(10) An application referred to in subregulation (1) shall be accompanied by one sample of such medicine subject to the provisions of regulation 6(2).

PARTICULARS TO BE PUBLISHED IN RESPECT OF APPLICATIONS RECEIVED FOR REGISTRATION REFERRED TO IN SECTION 14(3)

17. The following particulars with regard to applications for registration referred to in section 15(10) of the Act shall be published in the *Gazette*:

- (a) The proprietary name of the medicine;
- (b) the approved name and quantity of each active ingredient of the medicine contained in a dosage unit or per suitable mass or volume or unit;
- (c) the dosage form of the medicine;
- (d) the name of the applicant who lodged the application for registration;
- (e) the number allocated to it in terms of section 15 of the Act;
- (f) the name and address of the manufacturer;
- (g) the name of the person responsible for the final product release control; and
- (h) name of the person responsible for final product release responsibility.

INFORMATION THAT MUST APPEAR IN REGISTER FOR MEDICINES

18. The medicines register shall, in respect of any registered medicine, contain the following information:

- (a) The proprietary name of the medicine;
- (b) the registration number allocated to the medicine;
- (c) the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine;
- (d) the dosage form of the medicine;
- (e) the name of the holder of the certificate of registration;
- (f) the name and address of the manufacturer(s) and the manufacturing facilities;
- (g) the name of the final product release control;
- (h) the name of the final product release responsibility;
- (i) the date of registration of the medicine;
- (j) the conditions of registration of the medicine, as may have been determined in terms of section 15(6) of the Act;
- (k) category of the medicine;
- (l) class of the medicine; and
- (m) if falling under Category D a statement identifying the—
 - (i) sub-category of the medicine; and

- (ii) the associated discipline where applicable.

TRANSFER FROM REGISTER FOR MEDICINES TO REGISTER FOR MEDICAL DEVICES OR IVDs

19. (1) The Authority may transfer information pertaining to the registration of a medicine from the register for medicines to the register for medical devices or IVDs following an application for such transfer from the holder of the certificate of registration of the medicine.

(2) An application for transfer from the register for medicines to the register for medical devices and IVDs must be—

- (a) made to the Chief Executive Officer by the authorised representative;
- (b) on the application Form obtainable from the office of the Chief Executive Officer; and
- (c) accompanied by—
 - (i) the applicable certificate of registration;
 - (ii) the reasons for the transfer;
 - (iii) proposed classification of the medical device or IVD; and
 - (iv) the prescribed application fee.

(3) If the Authority approves the application submitted to him or her in terms of subregulation (2), the Chief Executive Officer shall make the necessary entries in the register relating to the medical device or IVD, cancel the existing certificate of registration and issue a new certificate of registration in the prescribed Form to such person.

(4) For the purposes of subregulation (2)(a) “authorised representative” shall be as defined in the Regulations Relating to Medical Devices and *In Vitro* Diagnostic Medical Devices (IVDs) in terms of the Act.

APPLICATION FOR AMENDMENT TO THE REGISTER FOR MEDICINES

20. (1) An application for the amendment of an entry in the register in terms of section 15A of the Act shall be accompanied by the relevant fee and must contain the following particulars—

- (a) the registration number of the medicine;
- (b) the name of the holder of the certificate of registration;
- (c) business address of the holder of the certificate of registration;

- (d) declaration by the holder of the certificate of registration that the information furnished is complete and accurate;
 - (e) the details of the amendment applied for; and
 - (f) any other information as may be required by the Authority.
- (2) Where a new certificate is issued in terms of section 15A(3) of the Act—
- (a) the original certificate of registration must be returned to the Authority; or
 - (b) if the original certificate of registration is lost, an affidavit must be submitted to the Authority confirming that the certificate of registration is lost.

CERTIFICATE OF REGISTRATION

21. A certificate of registration for medicines as contemplated in section 15(3) of the Act shall be in a form substantially similar to the form contained in Annexure 3.

LICENCE TO DISPENSE OR COMPOUND AND DISPENSE MEDICINES

22. (1) An application for a licence referred to in section 22C(1)(a) of the Act shall be made to the Director-General for a—

- (a) licence to dispense; or
- (b) licence to compound and dispense,

medicines in accordance with the relevant scope of practice of the applicant.

(2) An application referred to in subregulation (1) shall be accompanied by a prescribed application fee and contain at least the following information:

- (a) The name and both residential and business addresses (both physical and postal) of the applicant;
- (b) the exact location of the premises where dispensing, or compounding and dispensing will be carried out;
- (c) telephone number;
- (d) email address, if applicable;
- (e) fax number, if applicable; and
- (f) proof of registration with the relevant statutory health council.

(3) The application referred to in subregulation (1) may be submitted before a relevant supplementary course as contemplated in section 22C of the Act is completed, but may only be finally approved upon proof being furnished that such a course has been successfully completed and all other requirements have been met.

(4) A person referred to in subregulation (1) who has been issued with a licence shall—

- (a) keep a prescription book or permanent record as contemplated in regulation 35(1) relating to medicines dispensed, or compounded and dispensed for a period of 5 years from the date of sale;
- (b) ensure that the dispensary and any premises where medicines are kept are suitable for—
 - (i) dispensing; or
 - (ii) compounding and dispensing,in accordance with good pharmacy practice as published in rules in terms of the Pharmacy Act;
- (c) keep the medicines under the manufacturer's recommended storage conditions as specified on the medicines label and specified in the relevant professional information;
- (d) not repackage medicines at the premises unless authorised to do so in terms of regulation 39;
- (e) label medicines in terms of Regulation 10(6) where the reference number links to a patient record;;
- (f) dispense medicines in accordance with a prescription which complies with regulation 33 and based on a diagnosis for a particular patient;
- (g) not keep expired medicines on the premises other than in a demarcated area in a sealed container clearly marked: EXPIRED MEDICINES and such expired medicines must be destroyed in terms of regulation 44;
- (h) secure the premises where the dispensing or compounding and dispensing is carried out whenever he or she is not physically present at those premises;
- (i) in the event of a recall of a medicine, comply with the terms of the recall of the medicine;
- (j) conspicuously display the licence in the premises referred to in paragraph(b); and
- (k) comply with the conditions of the licence.

(5) A person who has been issued with a licence referred to in subregulation (1)(b) shall compound medicines—

- (a) only when the sale is preceded by a proper diagnosis and in accordance with a prescription which complies with regulation 33 for a particular patient; and
- (b) subject to regulation 3.

(6) For the purposes of this regulation, "dispensing" or "compounding and dispensing" does not refer to a medicine requiring preparation for a once-off administration to a patient during a consultation.

**LICENCE TO MANUFACTURE, IMPORT, EXPORT, ACT AS A WHOLESALER OF OR
DISTRIBUTE MEDICINES OR SCHEDULED SUBSTANCES**

- 23.** (1) An application for a licence referred to in section 22C(1)(b) of the Act, shall—
- (a) be made on a Form obtainable from the Authority for a licence—
 - (i) to manufacture, import or export a medicine or Scheduled substance;
 - (ii) to import a medicine or Scheduled substance;
 - (iii) to export a medicine or Scheduled substance; or
 - (iv) to act as a wholesaler of or distribute a medicine or Scheduled substance;
 - (b) be submitted to the Chief Executive Officer;
 - (c) be accompanied by documentary proof of—
 - (i) the particulars of the owner of the business;
 - (ii) registration of the responsible pharmacist with the South African Pharmacy Council;
 - (iii) qualifications of key personnel responsible for the manufacture, storage, distribution and sale of medicines or Scheduled substances in terms of the Act;
 - (iv) the ability to comply with good manufacturing, wholesaling or distribution practices as determined by Authority, which must include—
 - (aa) a copy of a local area plan of the location of the business premises indicating all adjacent properties and the nature of the business being carried on, on such properties;
 - (bb) a floor plan of the building in which the business premises are situated;
 - (cc) a plan of the actual layout of the business premises;
 - (dd) an inventory of equipment to be used in conducting the business; and
 - (ee) a manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of medicines, or Scheduled substances to be manufactured or distributed and sold;
 - (v) of the payment of the prescribed application fee;
 - (vi) any other information as may be requested by the Authority; and
 - (d) specify the medicines or Scheduled substance to be manufactured, imported, exported or distributed and sold.
- (2) The applicant contemplated in subregulation(1) shall—
- (a) appoint, and designate as such a responsible pharmacist who will control the importation, exportation, manufacturing, wholesaling, or distribution of medicines or Scheduled substances; and

- (b) appoint and designate a natural person who resides in the Republic, who shall be responsible to the Authority for compliance with the Act.
- (3) The Authority shall inspect the business premises specified in the application.
- (4) The Authority may issue a licence contemplated in subregulation (1) once the Authority is satisfied that the requirements of the Act and this regulation have been complied with.
- (5) The Chief Executive Officer shall—
 - (a) keep a separate register for each of the categories of licensees contemplated in section 22C(1)(b) of the Act; and
 - (b) enter the licence number, the name of the licensee and his or her physical and postal addresses, in the register contemplated in paragraph (a).
- (6) Notwithstanding the period of validity of the licence, the licensee must pay the prescribed annual fee for continued registration.
- (7) A holder of a licence in terms of subregulation (1) shall submit to the Chief Executive Officer an application, on a Form obtainable from the Authority, accompanied by the prescribed fee, in order to amend any of the following details of the licence:
 - (a) Name of the licence holder;
 - (b) responsible pharmacist;
 - (c) natural person in terms of subregulation (2)(b);
 - (d) site address;
 - (e) activities provided for by the licence; or
 - (f) the medicines or Scheduled substances to be manufactured, imported, exported or distributed and sold.
- (8) Following an application referred to in subregulation (7) the Authority may issue a new licence: Provided that—
 - (a) the Authority is satisfied that the application complies with provisions of subregulation (1) or any other conditions determined by the Authority;
 - (b) either—
 - (i) the original licence is returned to the Authority; or
 - (ii) an affidavit is submitted to the Authority stating that the original licence has been lost, if this is the case; and
 - (c) the applicable licence fee is paid.

(9) An applicant shall notify the Chief Executive Officer in writing of any change to any of the particulars furnished in the application contemplated in subregulation (1) within 30 days of such change.

(10) Any entry into the register in terms of subregulation (5) which is proved to the satisfaction of the Authority to have been made in error or through misrepresentation or in circumstances not authorised by the Act, may be removed from the register.

(11) A person in respect of whose entry a removal as contemplated in subregulation (10) has been made shall be notified of such removal and any licence issued in respect of this regulation shall be deemed to be cancelled as from the date on which notice has so been given.

(12) The Director-General or Chief Executive Officer, as the case may be, may make known to the public any information that pertains to the suspension or revocation of any licence referred to in this regulation in a manner which he or she thinks fit.

PERIOD OF VALIDITY AND RENEWAL OF LICENCE ISSUED IN TERMS OF REGULATIONS 22 AND 23

24. (1) A licence issued in terms of section 22C(1)(a) of the Act shall, provided that the holder pays the applicable annual fee, remain valid until it is suspended or revoked by the Director-General in terms of section 22E of the Act.

(2) A licence issued in terms of section 22C(1)(b) of the Act and referred to in regulation 7 shall, provided that the holder pays the applicable annual fee, be valid for a period of five years from the date of issue.

(3) A licence referred to in subregulation (1) or subregulation (2) which has expired may be renewed upon application to the Authority.

(4) An application referred to in subregulation (3) shall—

- (a) contain at least the information or documentation referred to in regulation 22(2) or 19(1)(c);
- (b) be accompanied by a fee prescribed in terms of section 35(1)(xxxii) of the Act; and
- (c) be made at least 180 days before the expiry of the existing licence.

(5) A licence referred to in subregulation (1) or subregulation (2) which has been revoked in terms of section 22E of the Act must be returned by the licensee to the Director-General or the Authority, as the case may be, without delay.

EXEMPTION IN TERMS OF SECTION 22H

25. (1) A wholesaler desiring to buy medicines from another wholesaler shall apply to the Director-General for an exemption referred to in section 22H(3) of the Act.

(2) An application referred to in subregulation (1) shall contain at least the following information:

- (a) Name and address (both physical and postal) of applicant;
- (b) name of the designated person;
- (c) the name and quantity of the medicines, to be bought;
- (d) source of supply; and
- (e) the reason for sourcing the medicine from another wholesaler.

(3) The Director-General may grant an exemption referred to in subregulation (1): Provided that such exemption is limited for a specific period of time as may be determined by the Director-General and—

- (a) it is intended to improve the availability of any medicine, Scheduled substance, medical device or IVD; and
- (b) is in the public interest.

PERMITS AND AUTHORISATION IN TERMS OF SECTION 22A

26. (1) (a) An application for a permit contemplated in section 22A(9)(a)(i) of the Act by a medical practitioner for the use of a Schedule 7 or 8 substance for the treatment or prevention of a medical condition in a particular patient shall contain at least the following information:

- (i) Name and address (both physical and postal) of the medical practitioner;
- (ii) identification number of the medical practitioner;
- (iii) registration number of the medical practitioner with statutory health council;
- (iv) qualifications of the medical practitioner;
- (v) contact details of the medical practitioner including the—
 - (aa) telephone number; and
 - (bb) facsimile number or email address;

- (vi) purpose for which the application is made;
 - (vii) the name and physical address of the patient, diagnosis, dosage and period of treatment; and
 - (viii) the place where and the manner in which the scheduled substances shall be stored safely.
- (b) The Director-General may issue a permit referred to in subregulation (1) only after consultation with the Authority.
- (c) A permit referred to in subregulation (1) may not be issued if the Director-General is of the opinion that the applicant is not capable of keeping or storing the substance in a manner so as to prevent the loss or diversion thereof.
- (2) (a) An application for a permit contemplated in section 22A(9)(a)(i) of the Act by a veterinarian for the use of a Schedule 7 or Schedule 8 substance for the treatment or prevention of a medical condition in a particular animal shall contain at least the following information:
- (i) Name and address (both physical and postal) of the veterinarian;
 - (ii) identification number of the veterinarian;
 - (iii) registration number of the veterinarian with the statutory council;
 - (iv) qualifications of the veterinarian;
 - (v) contact details of the veterinarian including the—
 - (aa) telephone number; and
 - (bb) facsimile number or email address;
 - (vi) purpose for which the application is made;
 - (vii) the name and address of the owner of the animal, diagnosis, dosage and period of treatment; and
 - (viii) the place where and the manner in which the scheduled substances shall be stored safely.
- (b) The Director-General may issue a permit referred to in paragraph (a) only after consultation with the Authority.
- (c) A permit referred to in paragraph (a) may not be issued if the Director-General is of the opinion that the applicant is not capable of keeping or storing the substance in a manner so as to prevent the loss or diversion thereof.
- (3) (a) An application for a permit contemplated in section 22A(9)(a)(i) of the Act by an analyst or researcher desiring to be provided with a Schedule 7 or Schedule 8

substance for the purposes of education, analysis or research, shall contain at least the following information:

- (i) Name and address (both physical and postal) of analyst or researcher;
- (ii) identification number of analyst or researcher;
- (iii) name and address of employer;
- (iv) qualifications of the analyst or researcher;
- (v) contact details of the analyst or researcher including the:
 - (aa) telephone number; and
 - (bb) facsimile number or email address;
- (vi) particulars of the intended education, analysis or research project;
- (vii) address at which the education, analysis or research will be undertaken;
- (viii) estimated duration of project or activity;
- (ix) total quantity of scheduled substances to be kept in stock per annum;
- (x) source of supply; and
- (xi) the place where and the manner in which the scheduled substances shall be stored safely.

(b) The Director-General may issue a permit referred to in paragraph (a) only after consultation with the Authority.

(c) A permit referred to in paragraph (a) may not be issued if the Director-General is of the opinion that the applicant is not capable of keeping or storing the substance in a manner so as to prevent the loss or diversion thereof.

(4) An application for a permit contemplated in section 22A(9)(a)(i) of the Act to manufacture any specified Schedule 5 or Schedule 6 substance shall contain at least the following information:

- (a) Name and address (both physical and postal) of the applicant;
- (b) name and registration number of the responsible pharmacist;
- (c) a certified copy of the manufacturing licence issued by the Authority in terms of section 22C(1)(b);
- (d) contact details of the applicant including the-
 - (i) telephone number; and
 - (ii) facsimile number or email address;
- (e) address at which manufacturing is to be undertaken; and
- (f) estimated quantity of specified Schedule 5 or Schedule 6 substance that will be manufactured.

- (5) (a) An application for a permit contemplated in section 22A(9)(a)(ii) of the Act to manufacture, use or supply a Schedule 5 or Schedule 6 substance for other than medicinal purposes shall contain at least the following information—
- (i) name and address (both physical and postal) of applicant;
 - (ii) contact details of the applicant, including the:
 - (aa) telephone number; and
 - (bb) facsimile number or email address;
 - (iii) name and address of contact person;
 - (iv) identification number of contact person;
 - (v) qualifications of the contact person;
 - (vi) contact details of the contact person, including the—
 - (aa) telephone number; and
 - (bb) facsimile number or email address; and
 - (vii) purpose for which the application is made.
- (b) The Director-General may issue a permit referred to in paragraph (a) only after consultation with the Authority.
- (6) (a) An application for a permit contemplated in section 22A(7)(a) of the Act shall contain at least the following information:
- (i) Name and address (both physical and postal) of applicant;
 - (ii) contact details of the applicant, including the—
 - (aa) telephone number; and
 - (bb) facsimile number or email address;
 - (iii) name and address of contact person;
 - (iv) identification number of contact person;
 - (v) qualifications of the contact person;
 - (vi) contact details of the contact person, including the—
 - (aa) telephone number; and
 - (bb) facsimile number or email address;
 - (vii) source of supply; and
 - (viii) the place where and the manner in which the scheduled substances shall be stored safely.

- (b) A permit referred to in paragraph (a) may not be issued if the Director-General is of the opinion that the applicant is not capable of keeping or storing the substance in a manner so as to prevent the loss or diversion thereof.
- (7) (a) An application for a permit contemplated in section 22A(15) of the Act shall contain at least the following information:
- (i) Name and address (both physical and postal) of applicant;
 - (ii) identification number of applicant;
 - (iii) name and address of employer;
 - (iv) qualifications of the applicant;
 - (v) proof of registration with the relevant statutory health council, if applicable
 - (vi) contact details of the applicant including the—
 - (aa) telephone number; and
 - (bb) facsimile number or email address;
 - (vii) source of supply; and
 - (viii) the place where and the manner in which the scheduled substances shall be stored safely.
- (b) A permit referred to in paragraph (a) may not be issued if the Director-General is of the opinion that the applicant is not capable of keeping or storing the substance in a manner so as to prevent the loss or diversion thereof.
- (c) A permit referred to in this subregulation may be withdrawn, revoked or suspended by the Director-General if the person issued with such a permit fails to comply with the conditions or requirements for issuing the permit.
- (8) A application for an authorisation contemplated in section 22A(10) of the Act shall contain at least the following information:
- (a) Name and address (both physical and postal) of medical practitioner;
 - (b) identification number of the medical practitioner;
 - (c) registration number of the medical practitioner with statutory health council;
 - (d) qualifications of the medical practitioner;
 - (e) contact details of the medical practitioner including the—
 - (i) telephone number; and
 - (ii) facsimile number or email address;
 - (f) purpose for which the application is made; and

- (g) the place where and the manner in which the scheduled substances shall be stored safely.

(9) Any permit holder or person referred to in this regulation may be subject to regular inspections of the premises or practice in terms of section 28 of the Act.

IMPORTATION OR EXPORTATION OF SPECIFIED SCHEDULE 5, SCHEDULE 6, SCHEDULE 7 OR SCHEDULE 8 SUBSTANCES

27. (1) An application for a permit contemplated in section 22A(11) of the Act shall contain at least the following information:

- (a) Name and address (both physical and postal) of the applicant;
- (b) name and registration number of the responsible pharmacist;
- (c) a certified copy of the licence issued by the Authority;
- (d) contact details of the applicant including the—
 - (i) telephone number; and
 - (ii) facsimile number or email address;
- (e) address at which such medicines will be stored;
- (f) estimated quantity of specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance that will be imported or exported; and
- (g) purpose for such importation or exportation.

(2) The applicant shall submit, with the application, a certified copy of the permit for exportation issued by the country from which the substance is to be exported.

INFORMATION TO BE FURNISHED ANNUALLY TO CHIEF EXECUTIVE OFFICER

28. (1) The holder of a permit referred to in regulation 27 shall furnish, annually, to the Chief Executive Officer, the following information:

- (a) The quantity of the substance, as a raw material or as contained in a preparation, which was held in stock on 1 January of the preceding calendar year;
- (b) the quantity of such substance acquired during the preceding calendar year by—
 - (i) importation of the substance, as a raw material or as contained in a preparation;
 - (ii) local production of the raw material; and

- (iii) local purchasing of the raw material, in which case the name of the supplier must also be furnished;
 - (c) the quantity of such substance, as a raw material or as contained in a preparation, which was disposed of during the preceding year through exportation or other means;
 - (d) the quantity of such substance used during the preceding calendar year in the production of any other Schedule 6 or Schedule 7 substance or a specified substance referred to in section 22A(12)(a)(ii) and (iii) of the Act; and
 - (e) the quantity of such substances and preparations containing such substances remaining in stock on 31 December of the preceding year.
- (2) The information referred to in subregulation (1) shall comply with the following requirements:
- (a) Quantities shall be expressed in metric units or as a percentage of the relevant substance;
 - (b) in the case of opium and any preparations containing opium, quantities must be expressed in terms of opium containing 10 per cent of anhydrous morphine;
 - (c) preparations not obtained directly from opium but from a mixture of opium alkaloids must be expressed in terms of morphine;
 - (d) quantities of coca-leaves must be expressed in terms of coca-leaves containing 0,5 percent of cocaine; and
 - (e) where stocks are held or manufacture has been undertaken on behalf of another person, this fact must be indicated.

AUTHORISATION OF SALE OF AN UNREGISTERED MEDICINE FOR CERTAIN PURPOSES

29. (1) Subject to the provision of information, requirements and conditions as determined by the Authority, a person desiring to sell an unregistered medicine subject to registration in terms of section 14 of the Act, for purposes other than a clinical trial, shall apply to the Authority, on an application form obtainable from the office of the Chief Executive Officer, for authorisation in terms of section 21 of the Act to sell such a medicine.

(2) An application referred to in subregulation (1) must be accompanied by the prescribed fee and must contain at least the following information—

- (a) duly completed application form;
- (b) product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human or animal pharmacological and clinical data with the medicine concerned;
- (c) witnessed informed consent document, where applicable;

- (d) details of registration or pending registration of the medicine with any other regulatory authority, if available;
 - (e) evidence of compliance of the manufacturer of the medicine with Good Manufacturing Practice standards as determined by the Authority;
 - (f) reasons why a South African registered medicine cannot be used; and
 - (g) any other information as may be required by the Authority.
- (3) The person under whose supervision the unregistered medicine or substance is prescribed shall submit to the Authority—
- (a) any adverse event report;
 - (b) progress reports after every six months from the date following commencement of the use of the unregistered medicine; and
 - (c) progress report 30 days after the completion or termination of the use of the medicine.
- (4) The Authority may—
- (a) impose any additional conditions;
 - (b) request additional information;
 - (c) inspect the site where the unregistered medicine is manufactured, stored or administered; or
 - (d) withdraw the authorisation to treat the patient or animal,

if the Authority is of the opinion that the safety of any patient or animal is compromised, that the scientific reasons for administering the unregistered medicine have changed or for any other reason as determined by the Authority.

(5) A medicine referred to in subregulation (1) shall be properly labelled and the package shall sufficiently identify the information as per the provisions of regulation 12(5)(c).

CONDUCT OF CLINICAL TRIALS FOR HUMANS AND ANIMALS

30. (1) A person desiring to initiate or conduct a clinical trial shall apply, on an application form obtainable from the office of the Chief Executive Officer, to the Authority for authorisation to conduct such a clinical trial.

(2) An application for a clinical trial shall be accompanied by a prescribed fee and contain at least the following information:

- (a) Clinical trial protocol;
- (b) investigator's brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human or animal

- pharmacological and safety and efficacy clinical data about the medicine concerned;
- (c) professional information pertaining to all registered medicines used in the trial or the international equivalent thereof if the medicines are not registered in South Africa;
 - (d) the details of the investigators who will be responsible for the sites where the trial is to be conducted and, in each case, who shall be—
 - (i) an appropriately qualified and competent person;
 - (ii) registered with the relevant statutory health council, where applicable; and
 - (iii) resident in the Republic;
 - (e) *Curriculum Vitae* of all investigators stipulated in terms of paragraph (d);
 - (f) proof of current training in Good Clinical Practice of all investigators;
 - (g) in the case of trials involving human participants, proof of current, relevant and appropriate—
 - (i) study insurance for all participants undertaken by the applicant referred to in subregulation (1); and
 - (ii) professional indemnity insurance for investigators;
 - (h) details of the site(s) where the trial is to be conducted;
 - (i) signed declaration by the applicant referred to in subregulation (1) and all investigators of the trial that they are familiar with and understand the protocol and will comply with Good Clinical Practice as determined by the Authority in the conduct of the trial;
 - (j) participant information form and informed consent documents in the case of human trials or owner consent document in the case of animal trials;
 - (k) approval of the clinical trial by—
 - (i) any health research ethics committee registered with the National Health Research Ethics Council in terms of the National Health Act, 2003 (Act No. 61 of 2003); or
 - (ii) in the case of research on animals, an Animal Ethics Committee, which must conform to SANS 10386:-2008; and
 - (l) any other information as may be required by the Authority.

(3) In the case of an application for a clinical trial in respect of a registered medicine, a registered indication or registered dosage regimen of a registered medicine or substance, subregulation (2) shall apply to the information contained in the application: Provided that it shall be sufficient to contain in the application form particulars referred to in subregulation (2) (a), (c), (d), (f), (h), (i), (k) and (l).

(4) Clinical trials shall be conducted in accordance with guidelines for good clinical practice as may be determined by the Authority from time to time.

(5) No person may conduct clinical trials referred to in subregulation (1) without the authorisation of the Authority.

(6) The person authorised by the Authority to conduct the clinical trial referred to in subregulation (1) shall submit—

- (a) progress reports to the Authority every six months from the date of approval of an application and 30 days after the completion or termination of the clinical trial;
- (b) a development safety update report annually and the final safety report 30 days after the completion or termination of the clinical trial; and
- (c) a final study report within 180 days of the completion or termination of the clinical trial.

(7) The principal investigator shall inform the Authority of any—

- (a) suspected adverse events; or
- (b) safety concerns,

occurring as a result of the use of any medicine during the conduct of a clinical trial.

(8) A person desiring to amend the protocol of a clinical trial referred to in subregulation (1) shall apply to the Authority together with the prescribed fee for the evaluation and authorisation related to such amendment.

(9) Medicines referred to in subregulation (1) shall be properly labelled and the package shall sufficiently identify the—

- (a) clinical trial to be carried out;
- (b) medicine(s) to be used;
- (c) participant number to whom the medicine is to be administered or in the case of animals the name of the person under whose supervision it is to be administered;
- (d) name and address of the site where the clinical trial is conducted;
- (e) the directions in regard to the manner in which such medicine should be used;
- (f) date of dispensing;
- (g) reference number; and
- (h) any other information as may be required by the Authority.

(10) The Authority may—

- (a) request additional information;
- (b) inspect a clinical trial site; or

(c) withdraw the authorisation to conduct a clinical trial,

if the Authority is of the opinion that the safety of the participants of the trial may be compromised or that the scientific reasons for conducting the trial have changed or if the integrity of the data is compromised.

OBTAINING PAIN CONTROL MEDICINES BY REGISTERED MIDWIVES

31. (1) Any person registered in the category, midwife in terms of the Nursing Act, 2005 (Act No. 33 of 2005), providing intra-partum care in accordance with the relevant scope of practice who wishes to purchase, acquire or keep for administration to patients Schedule 5 or Schedule 6 medicines for intra-partum care in accordance with the latest version of the Standard Treatment Guidelines/Essential Medicines List as approved by the National Essential Medicines List Committee shall apply in writing to the Director-General for a permit.

(2) An application referred to in subregulation (1) shall contain at least the following information:

- (a) The name of the applicant, together with proof of current registration with the South African Nursing Council;
- (b) the physical address of the premises where in or from which the midwifery services are rendered;
- (c) the nature of the midwifery services to be offered;
- (d) a list of conditions, including the relevant diagnostic codes that will be managed and for which access to Schedule 5 or Schedule 6 medicines is required per diagnostic code; and
- (e) the name and strength of every Schedule 5 or Schedule 6 medicine required.

(3) The Director-General may, upon receipt of such application and after making such inquiries as he or she may deem necessary, issue a permit authorising the applicant to purchase, acquire, keep or administer the requested Schedule 5 or Schedule 6 medicines.

(4) The permit shall be issued in a form as determined by the Director-General.

(5) A permit referred to in subregulation (3) shall be issued subject to the following conditions:

- (a) The holder of a permit issued in terms of sub-regulation (4) shall keep a register of medicines kept in a form as determined by the Authority, in which shall be entered at least the following particulars:
 - (i) Schedule number;

- (ii) name of medicine; and
 - (iii) strength;
- (b) the pharmacist supplying the Schedule 5 or Schedule 6 medicines may not supply a quantity more than that required for 30 days and shall enter the following particulars in a register kept by the midwife:
- (i) Date of supply;
 - (ii) number of permit;
 - (iii) quantity of medicine supplied;
 - (iv) name and address of pharmacy; and
 - (v) the pharmacist's signature;
- (c) the midwife shall sign in the presence of a pharmacist for receipt of the Schedule 5 or Schedule 6 medicines; and
- (d) the midwife shall enter the following particulars in the register after administration of the Schedule 5 or Schedule 6 medicines:
- (i) Date and time of administration;
 - (ii) name and address of patient;
 - (iii) quantity administered;
 - (iv) full signature;
 - (v) qualifications;
 - (vi) reason for administration; and
 - (vii) the balance on hand.

(6) The holder of a permit shall be personally responsible for keeping all medicines purchased or acquired in terms of a permit in safe-keeping.

(7) The holder of a permit shall at all times, at the request of any person duly authorised by the Director-General for purposes of inspection, produce the said permit, register and quantity of Schedule 5 or Schedule 6 medicines in his or her possession.

(8) The Director-General may at any time, by notice to the applicant cancel or withdraw the permit.

(9) On receipt of notification of cancellation or withdrawal, the holder of the permit shall return the permit and the register to the Director-General together with proof that any Schedule 5 or Schedule 6 medicines still in their possession has been handed over to a pharmacist for destruction in accordance with regulation 44.

(10) The Director-General shall keep a register of all permits issued to midwives.

(11) A permit issued in terms of this regulation shall be valid for a period of two years and may be renewed.

(12) A permit shall contain at least the following information:

- (a) Permit number;
- (b) the name, qualifications and official designation of the authorised official who issued such a permit, in an instance where the Director-General has delegated the power to issue such a permit;
- (c) the name, and address of the midwife;
- (d) the conditions that may be treated; and
- (e) the Schedule 5 or Schedule 6 medicines that may be purchased, and their strength, and dosage form.

ACQUISITION AND USE OF MEDICINES BY MASTERS OF SHIPS AND OFFICERS IN CHARGE OF ANY AIRCRAFT

32. A medical practitioner may, notwithstanding these Regulations, on the written request of a person in charge of, or the master of a ship or the officer in charge of an aircraft, authorise the purchase, acquisition, keeping or use of a Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance: Provided that the quantity shall be reasonable and on condition that such medicine is intended only for emergency medicinal use on board such ship or aircraft.

PARTICULARS WHICH MUST APPEAR ON PRESCRIPTION FOR MEDICINE

33. (1) Every prescription for a medicine shall be—
- (a) written in legible print;
 - (b) hand or typewritten; or
 - (c) prepared with an electronic agent as defined by and in compliance with the Electronic Communications and Transactions Act, 2002 (Act No. 25 of 2002).
- (2) A prescription shall be signed—
- (a) in person; or
 - (b) in the case of a prescription prepared in accordance with subregulation (1)(c), with an advanced electronic signature as per section 13 of the Electronic Communications and Transactions Act, 2002 (Act No. 25 of 2002),
- by an authorised prescriber.

- (3) A prescription shall at least state the following:
- (a) The name, qualification, registration number with the relevant statutory health council and address of the prescriber;
 - (b) the name, identification number and address of—
 - (i) the patient;
 - (ii) in the case of a prescription for a neonate, the parent or guardian; or
 - (iii) in the case of a prescription issued by a veterinarian, the person to whom the medicine or scheduled substance will be sold;
 - (c) the date of issue of the prescription;
 - (d) the approved name or the proprietary name of the medicine;
 - (e) the dosage form;
 - (f) the strength of the dosage form and the quantity of the medicine to be supplied: Provided that—
 - (i) in the case of a Schedule 6 substance the quantity to be supplied shall be expressed in figures as well as in words; and
 - (ii) where the prescriber has failed to express the quantity in figures as well as in words, the pharmacist dispensing the medicine may, after obtaining confirmation from the prescriber, insert the words or figures that have been omitted;
 - (g) instructions for the administration of the dosage, frequency of administration and the withdrawal period in the case of veterinary medicines for food producing animals;
 - (h) the age and gender of the patient and, in the case of veterinary medicine, the animal species; and
 - (i) the number of times the prescription may be repeated.

(4) The pharmacist who dispenses a prescription shall verify the authenticity of all prescriptions so dispensed.

(5) In the event of a prescription transmitted electronically by means other than an electronic agent in terms of subregulation (1), by fax or communicated verbally a permanent copy of the prescription shall be made for record purposes.

(6) A verbal prescription shall be followed by the signed prescription as per subregulation (2) within 7 working days from the communication.

(7) The prescriber shall keep records of the diagnosis relevant to the prescription and where the patient consents, indicate the diagnosis or the relevant diagnostic code on the prescription.

PARTICULARS WHICH MUST APPEAR ON ORDER FOR MEDICINE OR SCHEDULED SUBSTANCE

- 34.** (1) Every order for a medicine or scheduled substance shall be—
- (a) written in legible print;
 - (b) hand or typewritten; or
 - (c) prepared with an electronic agent as defined by and in compliance with the Electronic Communications and Transactions Act, 2002 (Act No. 25 of 2002).
- (2) An order for a medicine or scheduled substance shall be signed—
- (a) in person; or
 - (b) in the case of an order prepared in accordance with subregulation (1)(c), with an advanced electronic signature as per the Electronic Communications and Transactions Act, (Act No. 25 of 2002),
- by the pharmacist, pharmacist's assistant practising in accordance with the scope of practice prescribed in terms of the Pharmacy Act or authorised prescriber placing the order.
- (3) An order for a medicine or scheduled substance shall at least state the following:
- (a) The name, qualification registration number with a statutory health council and signature of an authorised person placing the order;
 - (b) the date of issue of the order;
 - (c) the approved name or the proprietary name of the medicine or scheduled substance;
 - (d) the dosage form;
 - (e) the strength of the dosage form and the quantity of the medicine to be supplied: Provided that, in the case of Schedule 6 substances,—
 - (i) the quantity to be supplied shall be expressed in figures, as well as in words; and
 - (ii) where the authorised person placing the order has failed to express the quantity in figures as well as in words, the pharmacist receiving the order, may after obtaining confirmation from the authorised person placing the order, insert the words or figures that have been omitted.
- (4) In the case of all orders, the pharmacist shall verify the authenticity of the order.

(5) In the event of an order transmitted electronically by means other than an electronic agent in terms of subregulation (1), by fax or communicated verbally, a permanent copy of the order shall be made for record purposes and shall be followed by the signed order as per subregulation (2) within 7 working days from the original transmission or communication.

PRESCRIPTION BOOK OR PERMANENT RECORD

35. (1) A prescription book or other permanent record in respect of Schedules 1, 2, 3, 4, 5 and 6 substances shall be kept in hard copy or electronically on all premises where such substances or medicines are sold or dispensed.

(2) In the case of Schedule 1 medicines and substances sold by any person other than a manufacturer or wholesaler, a prescription book or other permanent record contemplated in subregulation (1) shall contain the following particulars:

- (a) The name of the person to whom it was sold;
- (b) the name and quantity of the substance or medicine; and
- (c) the name of the pharmacist, pharmacist intern or pharmacist's assistant who sold it.

(3) In the case of Schedule 2, 3, 4 and 5 medicines and substances sold by any person other than a manufacturer or wholesaler, the prescription book or other permanent record contemplated in subregulation (1) shall contain the following particulars:

- (a) The name of the medicine or scheduled substance;
- (b) the date on which the prescription was dispensed;
- (c) the dosage form and quantity of the medicine or scheduled substance;
- (d) the name, identification number and address of—
 - (i) the patient;
 - (ii) in the case of a prescription for a neonate, the name, identification number and address a parent or guardian; or
 - (iii) in the case of a prescription issued by a veterinarian, the person to whom the medicine or scheduled substance was sold;
- (e) where applicable, the name of the medical practitioner, dentist, veterinarian or any other authorised person who issued the prescription; and
- (f) prescription reference number, which is the reference number or unique identifier assigned at the point of dispensing.

(4) The manufacturer or wholesaler shall keep an accessible permanent record of sales of Schedule 2, 3, 4, 5 and 6 medicines and substances in the form of invoices that shall reflect the—

- (a) date and transaction of the sale;
- (b) name of the medicine;
- (c) name and address of the purchaser;
- (d) quantities sold;
- (e) batch number; and
- (f) price at which the medicine was sold.

(5) A prescription book or other permanent record contemplated in this regulation shall be kept for a period of at least five years after the date of the last entry made therein.

REGISTER FOR SPECIFIED SCHEDULE 5 OR SCHEDULE 6 MEDICINES OR SUBSTANCES

36. (1) Any—

- (a) manufacturer, importer, exporter or wholesaler licensed in terms of section 22C(1)(b) of the Act selling specified Schedule 5 medicines or substances or Schedule 6 medicines or scheduled substances;
- (b) person selling specified Schedule 5 medicines or substances, other than a community or institutional pharmacy, or a person licensed in terms of section 22C(1)(a); or
- (c) person selling Schedule 6 medicines or substances,

shall keep a register of such medicines or substances.

(2) The register referred to in subregulation (1) shall—

- (a) indicate the quantity of every such medicine or substance remaining in stock on the last day of March, June, September and December of each year; and
- (b) contain the following information:
 - (i) the date on which the medicine or substance was received or supplied;
 - (ii) the name, business address of the person from whom the medicine or substance was received or sent and in the case of imported medicine or substance, the import permit number;
 - (iii) the name and address of the person who purchased the medicine or substance;
 - (iv) the quantity, in words and figures, of such medicine or substance indicated per dosage unit, mass or volume;
 - (v) in the case of the supply of the medicine or substance on prescription, the name and address of the authorised prescriber unless such prescription was issued at a hospital in which case the name of the authorised prescriber must be recorded;

- (vi) in the case of the manufacturer, the quantity of the medicine or substance manufactured or used during the manufacturing process; and
- (vii) any other information as may be required by the Authority.

(3) The register referred to in subregulation (1) shall be kept for a period of five years after the date of the last entry made therein.

(4) In a case where the register is kept electronically, a printout shall be made monthly, dated, signed and filed.

(5) Records must be stored in an orderly manner so that they can be accessed easily.

RETURNS TO BE FURNISHED IN RESPECT OF SPECIFIED SCHEDULE 5, SCHEDULE 6, SCHEDULE 7 OR SCHEDULE 8 SUBSTANCES

37. (1) No person may import, export, sell by wholesale, produce, manufacture or use, in the manufacture of any medicine or substance, any substance referred to in section 22A(12) of the Act unless the Authority is supplied with a return on or before 28 February of each year, reflecting the following information:

- (a) The quantity of such substance, as a raw material or as contained in a preparation, which was held in stock on 1 January of the preceding calendar year;
- (b) the quantity of such substance acquired during the preceding calendar year by—
 - (i) importation, as a raw material or contained in a preparation;
 - (ii) production of the raw material in the Republic; and
 - (iii) purchasing of the raw material in the Republic and the name of the supplier must be stated;
- (c) the quantity of such substance, as a raw material or as contained in a preparation, which was disposed of during the preceding calendar year through—
 - (i) exportation; or
 - (ii) destruction thereof;
- (d) the quantity of such substance used during the preceding calendar year in—
 - (i) the production of any other Schedule 6 or Schedule 7 substance or a specified substance referred to in section 22A(12) of the Act; and
 - (ii) the production of any other chemical substance not included in Schedule 6 or Schedule 7 or specified in section 22A(12)(a) of the Act; and

- (e) the quantity of such substance and preparations containing such substance remaining in stock on 31 December of the preceding year.

(2) Notwithstanding subregulation (1), the Authority may exempt an importer or exporter from furnishing a return, if the particular return is not necessary in determining the consumption of any of the substances included therein.

(3) The return referred to in subregulation (1) shall comply with the following requirements:

- (a) All quantities shall be expressed in metric units as a percentage base of the relevant substance;
- (b) in the case of opium and any preparations containing opium, quantities shall be expressed in terms of opium containing 10% of anhydrous morphine;
- (c) preparations obtained not directly from opium itself but by mixing opium alkaloids shall be expressed in terms of morphine;
- (d) in the case of any preparations of coca-leaves, quantities of coca-leaves shall be expressed in terms of coca-leaves containing 0,5% of cocaine; and
- (e) where stocks are held or manufacture has been undertaken on behalf of another applicant, this fact shall be indicated.

CONTROL OF MEDICINES IN HOSPITALS

38. The responsible pharmacist shall supervise the safety, security, purchasing, storage, compounding and dispensing of medicines in a hospital.

REPACKAGING OF MEDICINES INTO PATIENT-READY PACKS

39. The repackaging of medicines shall—

- (a) only be carried out by—
 - (i) a pharmacist, pharmacist intern or pharmacist's assistant under the supervision of a pharmacist; or
 - (ii) any other person authorised in terms section 29(4) of the Pharmacy Act;
- (b) have a batch numbering system which contains all the information linking the repackaged medicine with the original packaging thereof; and
- (c) be carried out in accordance with good manufacturing practice.

VIGILANCE

40. (1) A person who has applied for registration of a medicine in terms of section 15 of the Act, a holder of a certificate of registration in respect of a medicine or Scheduled substance, or a holder of a licence in terms of section 22C(1)(b) must inform the Authority, in the manner and within the time frame as determined by the Authority, of any—

- (a) new or existing quality, safety or effectiveness concerns related to any medicine or scheduled substance, including but not limited to adverse drug reactions; and
- (b) risk management activities associated with paragraph (a).

(2) A person who has applied for registration of a medicine in terms of section 15 of the Act, a holder of a certificate of registration in respect of a medicine or Scheduled substance, or a holder of a licence in terms of section 22C(1)(b) must maintain or have access to records of the reports and case reports referred to in subregulation (1) above.

(3) A health care provider, veterinarian or any other person should inform the Authority, in the manner as determined by the Authority, of any—

- (a) suspected adverse drug reactions; or
- (b) new or existing safety, quality or effectiveness concerns,

occurring as a result of the use of any medicine or scheduled substance.

(4) Any person referred to in subregulation (1) must—

- (a) whenever requested by the Authority, conduct a concise critical analysis of the safety, quality or effectiveness of the medicine or Scheduled substance submit the results thereof to the Authority within a specified time frame;
- (b) in the case where, after receipt of the results referred to in paragraph (a), the Authority determines that the medicine or Scheduled substance may not be safe to use, submit to the Authority, if required to do so—
 - (i) case reports of all adverse events or suspected or actual adverse drug reactions in respect of the medicine or Scheduled substance;
 - (ii) where applicable the usage figures of the medicines or Scheduled substance, as well as periodic safety update reports and performance studies; and
 - (iii) any other data as requested by the Authority; and
- (c) keep and maintain or have access to records of the adverse event data in respect of their medicines or Scheduled substances.

(5) Subregulations (1), (2) and (3) also apply in the case of all categories of unregistered medicines sold or used which are not subject to registration or in terms of sections 14(3), 14(4), 15C, 21 and 36 of the Act.

(6) Nothing in this regulation shall be interpreted as prohibiting any person from reporting any adverse drug reaction, safety, quality or effectiveness concern related to any medicine or Scheduled substance to the Authority.

PRICING COMMITTEE

41. (1) The pricing committee contemplated in section 22G of the Act shall consist of no more than eighteen members, but shall include—

- (a) one person nominated by the Minister of Finance;
- (b) one person nominated by the Minister of Trade and Industry;
- (c) one or more persons representing the Department of Health;
- (d) at least one person with background in pharmacology;
- (e) at least one person with background in the law;
- (f) at least one person with background in academic medical research;
- (g) at least two persons with economics background, one of whom must be a health economist; and
- (h) at least one person representing independent patient or consumer groups.

(2) The Committee shall determine the procedure for the conduct of its business.

(3) The Committee may appoint, subject to the approval of the Minister, subcommittees as it may deem necessary, to investigate and report to it any matter within the purview of the Committee in terms of the Act.

(4) The Director-General may designate employees of the Department to serve as the secretariat of the Committee.

ADVERTISING OF MEDICINES

42. (1) Medicines which contain a Schedule 0 substance or a substance listed as Schedule 1 may be advertised to the public.

(2) Medicines which contain a substance listed as Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 may be advertised—

- (a) only for the information of pharmacists, medical practitioners, dentists, veterinarians, practitioners, and other authorised prescribers; or

- (b) in a publication which is normally or only made available to persons referred to in paragraph (a).

(3) Subregulation (2) shall not be so construed as to prohibit informing the public of the prices, names, pack sizes and strengths of medicines which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 provided that no reference or inference is made to the registered indication.

(4) No advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine with regard to its safety, quality or efficacy where such evidence has been accepted by the Authority in respect of such medicine and incorporated into the approved professional information of such medicine.

- (5) An advertisement for a medicine shall contain—

- (a) the proprietary name of such medicine;

- (b) in the case of a written advertisement—

- (i) the approved name and quantity of each active ingredient of such medicine in lettering having minimum legibility: Provided that, in the case of a medicine containing only one active ingredient, such lettering shall be not less than one half the size of the largest lettering used for the said proprietary name;

- (ii) of a registered medicine, the registration number allocated to it in terms of section 15(5) of the Act;

- (iii) of a medicine in respect of which an application for registration has been submitted in terms of section 14 of the Act, the reference number allocated to such application by the Authority, followed by the words "Act 101/1965"; and

- (iv) where a name other than the proprietary name is also used, such other name shall be in lettering one half the size of the largest type size in which the proprietary name appears in such advertisement; and

- (c) in the case of a—

- (i) veterinary medicine, an indication that the medicine is for veterinary use; and

- (ii) complementary medicine—

- (aa) a statement identifying the discipline of the medicine where relevant;

- (bb) an indication that the medicine must be used in accordance with the applicable complementary discipline and principles where relevant; and

- (cc) if the medicine has not received registration with the Authority the following disclaimer:

"This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.";

(6) In the case of an advertisement for a medicine which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the Authority for inclusion in the professional information of such medicine.

(7) When a medicine is advertised verbally for the first time to persons contemplated to in subregulation 2(a), written information, which shall include at least the information referred to in regulation 11 or regulation 14, shall simultaneously be given to the person to whom the oral advertisement is directed, and when the medicine is advertised orally on subsequent occasions such information shall be available on request.

USE OF MEDICINES FOR EXHIBITION PURPOSES

43. A manufacturer, importer or wholesaler may use a medicine or scheduled substance sample for exhibition purposes or to introduce such medicine or scheduled substance to healthcare providers or the public: Provided that such samples—

- (a) are only meant for such exhibition or the launch of such medicine or scheduled substance; and
- (b) may not be handed out or given to any healthcare provider or member of the public.

DESTRUCTION OF MEDICINES OR SCHEDULED SUBSTANCES

44. (1) A medicine or scheduled substance shall only be destroyed by a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).

(2) No medicines or scheduled substances other than those as determined by the Authority shall be disposed of into municipal sewerage systems.

(3) The destruction or disposal of medicines or scheduled substances must be conducted in such a manner to ensure that the medicines or scheduled substances cannot be salvaged and the medicine or scheduled substance has been denatured.

(4) A Schedule 0 medicine or Schedule 1, 2, 3 or 4 substance or medicine must be destroyed at a site in terms of subregulation (1) and such destruction must be certified as determined by the Authority.

(5) A Schedule 5 or 6 substance or medicine shall be destroyed in terms of subregulation (1) in the presence of—

- (a) an inspector;
- (b) a pharmacist; or
- (c) any other person authorised by the Chief Executive Officer.

(6) A Schedule 7 or 8 substance or medicine shall be destroyed in terms of subregulation (1) in the presence of—

- (a) an inspector;
- (b) two pharmacists; or
- (c) any other person authorised by the Chief Executive Officer.

(7) The waste treatment facility shall issue a certificate and maintain a record of the destruction contemplated in subregulations (4), (5) and (6) which shall contain the following information:

- (a) the name of the medicine or scheduled substance, if known; or the schedule of the medicine or scheduled substance concerned;
- (b) the quantity destroyed;
- (c) the date of destruction of the medicine or scheduled substance;
- (d) the name and designation of the person in whose presence such destruction took place; and
- (e) any other information as determined by the Authority.

SKILLS OF STAFF OF AUTHORITY

45. (1) For purposes of providing monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, medical devices and IVDs, the Authority shall ensure that staff are appointed with the necessary qualification, expertise in and knowledge of—

- (a) clinical medicine;
- (b) clinical pharmacology;
- (c) pharmaceutical chemistry;
- (d) toxicology and medicine or scheduled substance safety;
- (e) biotechnology;
- (f) pharmaceuticals;
- (g) adverse drug reactions and vigilance;

- (h) virology and microbiology;
- (i) veterinary clinical pharmacology;
- (j) good manufacturing practices, clinical and laboratory practices;
- (k) biomedical or clinical engineering;
- (l) medical technologist;
- (m) investigations on matters relating to legislation;
- (n) complementary medicines; or
- (o) other appropriate skills as required by the Authority from time to time.

(2) For purposes of oversight, leadership and accountability, the Authority shall ensure that staff are appointed with the necessary qualification, expertise and knowledge relating to at least—

- (a) operational management;
- (b) supply chain and asset management;
- (c) financial management;
- (d) human resource management;
- (e) information and record management; and
- (f) knowledge in law.

TIME FRAMES FOR CONSIDERING APPLICATIONS

46. (1) The Authority shall as soon as practically possible and in accordance with a timeframe as determined by the Authority inform any applicant of the receipt of an application for the registration of a medicine, medical device and IVD.

(2) The Authority shall as soon as practically possible and in accordance with a timeframe as determined by the Authority after receipt of the application by the Authority inform any applicant in respect of any application referred to in subregulation (1) on the acceptance of the application for evaluation.

APPEAL AGAINST DECISION OF DIRECTOR-GENERAL

47. (1) An appeal against a decision of the Director-General shall be lodged with the Minister within 30 days from the date on which the written decision appealed against was received by the person concerned, and such a person shall at the same time submit a copy of the appeal to the Director-General.

- (2) The appeal contemplated in subregulation (1) shall—
- (a) be lodged in writing;

- (b) state the full name, address and contact number of the person lodging the appeal;
 - (c) state the decision appealed against;
 - (d) contain the reasons furnished by the Director-General for the decision, if possible;
 - (e) state the ground for appeal;
 - (f) be addressed to the Minister: National Department of Health and delivered by hand, post, faxed or electronically mail to one of the following addresses respectively:
 - (i) physical address of the National Department of Health;
 - (ii) Department of Health, Private Bag X828, Pretoria, 0001; or
 - (iii) email address: minister@health.gov.za; copied to DG@health.gov.za.
- (3) The copy of the appeal contemplated in subregulation (1) shall be—
- (a) sent by registered mail to the Director-General, Department of Health, Private Bag X828, Pretoria, 0001; or
 - (b) hand delivered to the Director-General at the physical address of the National Department of Health.
- (4) The Director-General shall, within 30 days of receipt of the copy of the appeal, furnish the Minister with his or her reasons for the decision.
- (5) The Minister shall, within 30 days of receipt of the reasons referred to in subregulation (4), confirm, set aside or vary the decision of the Director-General.
- (6) The Minister shall, in writing and within 10 days of his or her decision contemplated in subregulation (5), inform the person who lodged the appeal of his or her decision and the reasons therefor.

APPEAL AGAINST DECISION OF AUTHORITY

- 48.** (1) The appeal committee referred to in section 24A(3) of the Act, shall be appointed within 30 days of receipt of the notice referred to in the said section.
- (2) The appeal committee—
 - (a) shall determine the procedure for its hearings;
 - (b) may, if it deems necessary, call for oral evidence or argument or summon any person who—

- (i) in its opinion may be able to give information concerning the subject of the appeal; or
 - (ii) it believes has in his or her possession or under control any document which has a bearing on the subject of the appeal, to appear before it at a time and place specified in the summons, to be asked questions or to produce any such document; and
- (c) shall, if it calls for oral evidence or argument,—
- (i) determine the date, time and place for the appeal and shall communicate these in writing to the appellant and the Minister; and
 - (ii) administer an oath to or accept an affirmation from any person called as a witness at the appeal.
- (3) Persons appearing before an appeal committee may be represented by a legal practitioner.
- (4) The Appeal Committee may—
- (a) set aside or confirm the decision of the Authority;
 - (b) vary the decision of the Authority;
 - (c) direct the Authority to reconsider any matter; or
 - (d) make any finding that is just and equitable in the circumstances.

INVESTIGATIONS

- 49.** The Authority may conduct an investigation with regard to a medicine or a Scheduled substance if—
- (a) such a medicine or Scheduled substance is recalled in South Africa or any other country;
 - (b) any adverse drug reaction is reported;
 - (c) the medicine or Scheduled substance is suspected or found not to comply with the requirements of the Act;
 - (d) there is an international alert with regard to such a medicine or Scheduled substance; or
 - (e) for any other reason related to the safety, quality and efficacy of medicine or a Scheduled substance, the Authority deems it fit to conduct an investigation on the medicine or Scheduled substance.

METHOD OF TAKING SAMPLES, CERTIFICATE TO BE ISSUED AND REPORTING OF ANALYSIS RESULTS

50. (1) An inspector may take a sample or any quantity of samples of a medicine or Scheduled substance for purposes of testing, examination or analysis in terms of the Act by a person designated as an analyst, pharmacologist or pathologist.

- (2) The sample or samples contemplated in subregulation (1) shall—
 - (a) be taken in the presence of the person who is in charge of such medicine or substance, or in the absence of such person, in the presence of any witness present;
 - (b) be taken, transported and stored in such a manner as to ensure its integrity during the entire examination process of the sample; and
 - (c) be packed and sealed and suitably labelled or marked in such a manner as its nature may permit;
 - (d) be transmitted by any suitable means to an analyst, pharmacologist or pathologist; and
 - (e) be accompanied with the certificate signed by the inspector, a copy of which shall be issued to the person contemplated in paragraph (a) by the inspector at the earliest possible time.

(3) An analyst, pharmacologist or pathologist referred to in subregulation (1) shall, as soon as possible after receipt of the sample, test, examine or analyse the sample and report the results thereof to the Authority.

(4) An inspector referred to in subregulation (1), may take a sample during a routine inspection from a manufacturer, a wholesaler or retailer for testing, examination or analysis in terms of these regulations.

(5) Notwithstanding subregulation (1), the Authority may require any holder of a certification of registration to supply the Authority with a sample of a particular medicine or substance in order to test, examine or analyse such sample.

(6) Certificates or reports issued in terms of this regulation shall be submitted to the Chief Executive Officer within 7 days from the date of issue.

SEIZURE OF MEDICINES

- 51.** (1) A medicine may be seized if it—
- (a) is sold in contravention of the Act;

- (b) is suspected of being a counterfeit;
- (c) is misbranded, sub-standard or adulterated;
- (d) has expired;
- (e) is suspected stolen;
- (f) is Scheduled and is sold—
 - (i) by an unauthorised person;
 - (ii) by an authorised person but in unauthorised quantities; or
 - (iii) at an unauthorised place or site;
- (g) has been declared undesirable in terms of the Act;
- (h) belongs to the State and is found to be possessed by an unauthorised person; or
- (i) is used in an unauthorised clinical trial.

(2) An inspector seizing any item in terms of section 28(1)(c) of the Act shall, as soon as possible and at the scene of seizure, make a written inventory of all items seized and the inventory shall include—

- (a) the date, place and time of seizure;
- (b) the name and personal details of the person from whom the items were seized;
- (c) the name and quantity of every item seized; and
- (d) the name of the inspector conducting the seizure.

(3) An item contemplated in subregulation (2) may be used as evidence in any criminal proceedings in terms of this Act.

(4) An inspector taking any sample in terms of section 28(1)(d) of the Act shall make a written inventory of all samples taken which inventory shall include—

- (a) the date on which, the place where and time when the sample was taken;
- (b) a description of nature and size of each sample taken; and
- (c) the personal details of the person in whose presence the sample was taken; and the name of the inspector taking the sample.

OFFENCES AND PENALTIES

52. Any person who fails to comply with, contravenes the provisions of or furnishes incorrect information, as the case may be, in respect of—

- (a) regulation 5(1)(c) or (d) with regard to the parallel importation of medicines;
- (b) regulations 6 or 7 with regard to the importation or transmission of medicines;

- (c) regulation 8 with regard to the possession of specified quantities of Schedule substances for personal medicinal use by persons entering the Republic;
- (d) regulation 10 with regard to the labelling of medicines for human use;
- (e) regulation 11 with regard to the professional information to be provided;
- (f) regulation 12 with regard to the patient information leaflet;
- (g) regulation 13 with regard to the labelling of veterinary medicines;
- (h) regulation 14 with regard to the professional information for veterinary medicines;
- (i) regulation 22 with regard to the licence to dispense, or compound and dispense medicines;
- (j) regulation 23 with regard to the licence to manufacture, import or export act as a wholesaler or distribute medicines or Scheduled substances;
- (k) regulation 26 with regard to the permits or authorisation issued in terms of section 22A of the Act;
- (l) regulation 27 with regard to the importation or exportation of specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substances;
- (m) regulation 28 with regard to the information to be furnished annually to the Director-General by the holder of a permit to import or export specified Schedule 5, Schedules 6, 7 or 8 substances;
- (n) regulation 29 with regard to authorisation of sale of unregistered medicine for certain purposes;
- (o) regulation 30 with regard to the conduct of clinical trials;
- (p) regulation 33 or 34 with regard to the particulars which must appear on a prescription or order for medicine;
- (q) regulation 35 with regard to the prescription book or permanent record;
- (r) regulation 36 with regard to the register for specified Schedule 5 and 6 medicines;
- (s) regulation 37 with regard to the returns to be furnished in respect of specified Schedule 5, Schedules 6, 7 and 8 medicines and specified substances;
- (t) regulation 39 with regard to the repackaging of medicines;
- (u) regulation 42 with regard to the advertising of medicines or Scheduled substances;
- (v) regulation 44 with regard to the destruction of medicines or Scheduled substances; or
- (w) sells a medicine that has expired,

shall be guilty of an offence and upon conviction be liable to a fine or to imprisonment for a period not exceeding 10 years.

COMPLIANCE WITH REQUIREMENTS

53. (1) Every medicine must continue to comply with the standards and specifications which were furnished to the Authority and which have been accepted by the Authority with regard to such medicine.

(2) Any proposed deviation from accepted standards and specifications referred to in subregulation (1) must be submitted to the Authority for prior approval as determined by the Authority and such deviation must not be introduced before the said approval has been granted.

REPEAL

54. The Regulations published under Government Notice No. R 510 of 10 April 2003 in *Government Gazette* No. 24727 are hereby repealed.



DR A MOTSOLEDI, MP

MINISTER OF HEALTH

DATE: 22/7/2017

SCHEDULES

Annexure 1

Classes of Medicines in categories A and D (human complementary medicine)

1. Central nervous system stimulants

- 1.1 Central analeptics.
- 1.2 Psychoanaleptics (antidepressants).
- 1.3 Special antidepressant combinations.
- 1.4 Respiratory stimulants.
- 1.5 Hallucinogenic medicines.
- 1.6 Other central nervous system stimulants.

2. Central nervous system depressants

- 2.1 Anaesthetics.
- 2.2 Sedatives, hypnotics.
- 2.3 Barbiturates.
- 2.4 Non-barbiturates.
- 2.5 Anticonvulsants, including anti-epileptics.
- 2.6 Tranquillisers.
 - 2.6.1 Phenothiazines and their derivatives.
 - 2.6.2 Rauwolfia: Alkaloids and combinations.
 - 2.6.3 Diphenylmethane and its derivatives.
 - 2.6.4 Alkyl diols and their derivatives.
 - 2.6.5 Miscellaneous structures.
- 2.7 Antipyretics or antipyretic and anti-inflammatory analgesics.
- 2.8 Analgesic combinations.
- 2.9 Other analgesics.
- 2.10 Centrally acting muscle relaxants.
- 2.11 Other medicines acting on the central nervous system
- 2.12 Depressants.

3. Connective Tissue Medicines

- 3.1 Antirheumatics (anti-inflammatory agents).

- 3.2 Non-hormonal preparations.
- 3.3 Anti-gout preparations.
- 3.4 Combinations with corticosteroids.
- 3.5 Others.

4. Local anaesthetics

5. Medicines affecting autonomic function

- 5.1 Adrenomimetics (sympathomimetics).
- 5.2 Adrenolytics (sympatholytics).
- 5.3 Cholinomimetics (cholinergics).
- 5.4 Cholinolytics (anticholinergics).
 - 5.4.1 Anti-Parkinsonism preparations.
 - 5.4.2 General.
- 5.5 Ganglion blockers.
- 5.6 Histamine.
- 5.7 Antihistaminics, anti-emetics and antivertigo preparations.
 - 5.7.1 Antihistaminics.
 - 5.7.2 Anti-emetics and antivertigo preparations.
- 5.8 Preparations for the common cold including nasal decongestants.
- 5.9 Hydroxytryptamine (serotonin).
- 5.10 Serotonin antagonists.
- 5.11 Others.

6. Cardiac medicines

- 6.1 Cardiac stimulants.
- 6.2 Cardiac depressants.
- 6.3 Cardiac glycosides.
- 6.4 Antidysrhythmics/conduction modifying medicines.
- 6.5 Others.

7. Vascular medicines

- 7.1 Vasodilators, hypotensive, antihypertensive medicines include other antihypertensive medicines e.g. ACE-inhibitors, ARBs, RAAS, etc]
 - 7.1.1 Rauwolfia and combinations.

- 7.1.2 Rauwolfia: Diuretic combinations.
- 7.1.3 Other hypotensives.
- 7.1.4 Vasodilators - coronary and other medicines used in angina pectoris.
- 7.1.5 Vasodilators - peripheral.
- 7.2 Vasoconstrictors, pressor medicines.
- 7.3 Migraine preparations.
- 7.4 Lipotropic agents.
- 7.5 Serum-cholesterol reducers.
- 7.6 Others.

8. Medicines acting on blood and haemopoietic system

- 8.1 Coagulants, haemostatics.
- 8.2 Anticoagulants.
- 8.3 Erythropoietics (haematinics).
- 8.4 Plasma expanders.
- 8.5 Others.

9. Medicines against alcoholism

10. Medicines acting on respiratory system

- 10.1 Antitussives and expectorants.
- 10.2 Bronchodilators.
 - 10.2.1 Inhalants.
- 10.3 Others.

11. Medicines acting on gastro-intestinal tract

- 11.1 Digestants.
- 11.2 Gastro-intestinal antispasmodics and cholinolytics (anticholinergics).
- 11.3 Anorexigenics.
- 11.4 Antacids.
 - 11.4.1 Acid neutralisers.
 - 11.4.2 Acid neutralisers with antispasmodics.
 - 11.4.3 Other.
- 11.5 Laxatives.
- 11.6 Lubricants and faecal softeners.

- 11.7 Cholagogues.
- 11.8 Suppositories and anal ointments.
- 11.9 Antidiarrhoeals.
 - 11.9.1 Antidiarrhoeals in combination with anti-infective agents.
 - 11.9.2 Special combinations.
- 11.10 Others.

12. Anthelmintics, bilharzia medicines, filaricides, etc.

13. Dermatological preparations

- 13.1 Antiseptics, disinfectants and cleansing agents.
- 13.2 Antiscabies medicines.
- 13.3 Surface anaesthetics.
- 13.4 Antipruritics.
 - 13.4.1 Corticosteroids with or without anti-infective agents.
 - 13.4.2 Emollients and protectives.
- 13.5 Rubefacients.
- 13.6 Counterirritants.
- 13.7 Keratolytics.
- 13.8 Special combinations.
 - 13.8.1 Preparations for psoriasis.
 - 13.8.2 Fungicides.
- 13.9 Radiation protectants.
- 13.10 Melanin inhibitors and stimulants.
- 13.11 Acne preparations.
- 13.12 Others.

14. Preparations for treatment of wounds

- 14.1 Wound disinfectants.
- 14.2 Wound dressings.
- 14.3 Others.

15. Ophthalmic preparations

- 15.1 Ophthalmic preparations with antibiotics and/or sulphonamides.
- 15.2 Ophthalmic preparations with corticosteroids.

15.3 Combination antibiotics.

15.4 Others.

16. Ear, nose and throat preparations

16.1 Nasal decongestants.

16.2 Aural preparations.

16.3 Surface anaesthetics.

16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics.

16.5 Others.

17. Medicines acting on muscular system

17.1 Peripherally acting muscle relaxants.

17.2 Muscle activators.

17.3 Others.

18. Medicines acting on reno-urinary and genital system

18.1 Diuretics.

18.2 Antidiuretics.

18.3 Ion-exchange preparations.

18.4 Urolitholytics.

18.5 Urinary tract antiseptics.

18.6 Vaginal preparations.

18.7 Contraceptive preparations.

18.8 Ovulation controlling agents.

18.9 Uterine antispasmodics.

18.10 Others.

19. Oxytocics

20. Antimicrobial (chemotherapeutic) agents

20.1 Antibiotics and antibiotic combinations.

20.1.1 Broad and medium spectrum antibiotics.

20.1.2 Penicillins.

20.1.3 Penicillin-streptomycin combinations.

20.1.4 Antibiotic-sulphonamide combinations.

- 20.1.5 Streptomycin and combinations.
- 20.1.6 Topical antibiotics.
- 20.1.7 Antifungal antibiotics.
- 20.2 Other than antibiotics.
 - 20.2.1 Sulphonamides.
 - 20.2.2 Fungicides.
 - 20.2.3 Tuberculostatics.
 - 20.2.4 Leprostatics.
 - 20.2.5 Germicides.
 - 20.2.6 Medicines against protozoa.
 - 20.2.7 Spirochaeticides.
 - 20.2.8 Antiviral agents.
- 20.3 Others.

21. Hormones, antihormones and oral hypoglycaemics

- 21.1 Insulin preparations.
- 21.2 Oral hypoglycaemics.
- 21.3 Thyroid preparations.
- 21.4 Parathyroid preparations.
- 21.5 Corticosteroids.
 - 21.5.1 Corticosteroids and analogues.
 - 21.5.2 Analgesic combinations.
 - 21.5.3 Anti-infective combinations.
- 21.6 Anabolic steroids.
- 21.7 Male sex hormones.
- 21.8 Female sex hormones.
 - 21.8.1 Oestrogens.
 - 21.8.2 Progesterones with or without oestrogens.
- 21.9 Androgen-oestrogen combinations.
- 21.10 Trophic hormones.
- 21.11 Hyperglycaemic hormones.
- 21.12 Hormone inhibitors.
- 21.13 Others.

22. Vitamins

22.1 Multivitamins and multivitamins with minerals.

22.1.1 Vitamins for paediatric use.

22.1.2 Vitamins for prenatal use.

22.1.3 Vitamins for geriatric use.

22.1.4 Vitamin B-complex with Vitamin C.

22.2 Others.

23. Amino-acids**24. Mineral substitutes, electrolytes and trace elements****25. Special foods**

25.1 Infant foods and other formulae, excluding foods used solely as a substitute for human milk.

26. Cytostatic agents**27. Chelating agents (versenates) as heavy metal antidotes****28. Contrast media****29. Diagnostic agents****30. Biologicals**

30.1 Antibodies.

30.2 Antigens.

30.3 Blood fractions.

30.4 Probiotics.

30.5 Others.

31. Enzymatic preparations**32. Other substances or agents**

32.1 Tonics.

- 32.3 Slimming preparations.
- 32.4 Water for injection.
- 32.5 Artificial tear and contact lens solutions.
- 32.6 Preparations of boracic acid, borax and zinc, starch and boracic powder.
- 32.7 Topical applications of delousing agents.
- 32.8 Topical applications of insect repellents.
- 32.9 Intra-uterine devices.
- 32.10 Dental preparations.
- 32.11 Solutions for haemo- or peritoneal dialysis.
- 32.12 Preparations for which the expressions "medicated", "medicinal", "for medical use" or expressions with similar connotations are used.
- 32.13 Preparations intended to promote hair growth.
- 32.14 Sales packs containing two or more medicines with different indications.
- 32.15 Radiopharmaceuticals.
- 32.16 Others.

33. Complementary Medicines: Discipline-Specific Traditional Claims

- 33.1 Aromatherapy
- 33.2 Homeopathy
- 33.3 Phytotherapy
- 33.4 Traditional Chinese Medicine
- 33.5 Unani Medicine
- 33.6 Western Herbal Medicine
- 33.7 Combination Product
- 33.8 Other Herbal

34. Complementary Medicines: Health Supplements

- 34.1 Amino acids
- 34.2 Aminosaccharides
- 34.3 Animal Extracts, Products and Derivatives
- 34.4 Carotenoids
- 34.5 Enzymes
- 34.6 Fats, Oils and Fatty Acids
- 34.7 Minerals
- 34.8 Polyphenols (including Bioflavonoids)
- 34.9 Probiotics

- 34.10 Saccharides (including prebiotics)
- 34.11 Vitamins
- 34.12 Multiple substance formulation
- 34.13 Other

Annexure 2

Classes of Medicines in categories C and D (veterinary complementary medicines)

1. Central and Peripheral Nervous System

- 1.1 Central nervous system stimulants.
 - 1.1.1 Central analeptics.
 - 1.1.2 Respiratory Stimulants.
- 1.2 Anaesthetics.
 - 1.2.1 Inhalation anaesthetics.
 - 1.2.2 Parenteral anaesthetics.
 - 1.2.3 Local anaesthetics.
- 1.3 Narcotic analgesics.
 - 1.3.1 Opioid agonists.
 - 1.3.2 Opioid antagonists.
- 1.4 Sedatives.
 - 1.4.1 Sedative hypnotics.
 - 1.4.2 Sedative analgesics.
 - 1.4.3 Sedative antagonists.
- 1.5 Anticonvulsants including anti-epileptics.
- 1.6 Tranquillisers.
 - 1.6.1 Phenothiazine derivatives.
 - 1.6.2 Butyrophenone derivatives.
- 1.7 Neuroleptanalgesics.
- 1.8 Analgesic antipyretics.
- 1.9 Medicines used for euthanasia.

2. Autonomic Nervous System

- 2.1 Sympathomimetics.
- 2.2 Sympatholytics.
- 2.3 Cholinergics.
- 2.4 Antimuscarinics.

3. Musculo-Skeletal System and Joints

- 3.1 Anti-inflammatory.
 - 3.1.1 Steroidals.

- 3.1.2 Non-steroidal anti-inflammatory drugs (NSAIDs).
 - 3.1.2.1 Non selective COX2 inhibitors.
 - 3.1.2.2 Selective COX2 inhibitors.
- 3.1.3 Topical agents.
- 3.1.4 Combinations.
- 3.1.5 Other.
- 3.2 Analgesics
 - 3.2.1 Opioids.
 - 3.2.2 NSAIDs.
 - 3.2.3 Topical agents.
 - 3.2.4 Combinations.
- 3.3 Muscle relaxants.
 - 3.3.1 Centrally acting.
 - 3.3.2 Peripherally-acting.

4. Autacoids

- 4.1 Histamine inhibitors.
 - 4.1.1 Antihistamines.
 - 4.1.2 Histamine release inhibitors.
- 4.2 Serotonin antagonists.
- 4.3 Others.

5. Cardio-Vascular System

- 5.1 Positive inotropic agents.
 - 5.1.1 Cardiac glycosides.
 - 5.1.2 Methylxanthines.
 - 5.1.3 Others.
- 5.2 Anti-arrhythmics.
- 5.3 Vasodilators.
 - 5.3.1 Peripheral-acting vasodilators.
 - 5.3.2 Angiotensin inhibitors.
 - 5.3.3 Calcium channel inhibitors.

6. Blood And Haemopoietic System

- 6.1 Coagulants, haemostatics.

- 6.2 Anticoagulants.
- 6.3 Haematinics.
- 6.4 Plasma expanders.

7. Respiratory System

- 7.1 Antitussives and expectorants.
- 7.2 Mucolytics.
- 7.3 Bronchodilators.
- 7.4 Combinations.

8. Gastro-Intestinal System

- 8.1 Mouth washes.
- 8.2 Emetics.
- 8.3 Anti-emetics.
- 8.4 Acid-reducers.
 - 8.4.1 Antacids and combinations.
 - 8.4.2 Histamine-2 receptor antagonists.
 - 8.4.3 Proton pump inhibitors.
 - 8.4.4 Cytoprotective agents.
- 8.5 Motility enhancers.
 - 8.5.1 Lubricants and Faecal softeners.
 - 8.5.2 Laxatives and Purgatives.
- 8.6 Antispasmodics.
- 8.7 Antidiarrhoeals.
 - 8.7.1 Plain.
 - 8.7.2 With anti-microbial agents.
 - 8.7.3 Antimicrobial agents.
 - 8.7.4 Biologicals.
- 8.8 Analgesics.
- 8.9 Digestants.
- 8.10 Preparations used in the rumen.
 - 8.10.1 Ruminotorics.
 - 8.10.2 Anti-bloat remedies.
 - 8.10.3 Others.

9. Hepatic System

- 9.1 Cholagogues and cholerectics.
- 9.2 Liver protectants and lipotropics.

10. Urinary System

- 10.1 Diuretics.
- 10.2 Urolitholytics and antispasmodics.
- 10.3 Urinary tract antiseptics.
- 10.4 pH modifiers.
 - 10.4.1 Urinary acidifiers.
 - 10.4.2 Urinary alkalinisers.
- 10.5 Others.

11. Reproductive System

- 11.1 Intravaginal and intra-uterine preparations.
- 11.2 Sex hormones.
 - 11.2.1 Testosterone.
 - 11.2.2 Oestrogens.
 - 11.2.3 Progesterones and Progestogens.
 - 11.2.4 Combinations.
- 11.3 Prostaglandins.
- 11.4 Trophic hormones.
- 11.5 Myometrial stimulants (Ecbolics).
- 11.6 Myometrial relaxants (Tocolytics).
- 11.7 Ovulation controlling agents.

12. Endocrine System

- 12.1 Insulin preparations.
- 12.2 Thyroid preparations.
- 12.3 Corticosteroids.
- 12.4 Growth Hormone.
- 12.5 Anabolic steroids.

13. Dermatologicals

- 13.1 Disinfectants and cleaning agents.

- 13.2 Antiseptic and antimicrobial preparations.
- 13.3 Antipuritics.
 - 13.3.1 Topical corticosteroids with or without anti-infective agents.
 - 13.3.2 Topical antihistamines with or without anti-infective agents.
- 13.4 Emollients and protectives.
- 13.5 Rubefacients and counter irritants.
- 13.6 Keratolytics.
- 13.7 Antifungals.
- 13.8 Anti-parasitics.

14. Ophthalmic And Aural Preparations

- 14.1 Anti-infectives.
- 14.2 Corticosteroids.
- 14.3 Combinations (anti-infective with corticosteroids).
- 14.4 Others.

15. Wounds

- 15.1 Wound antiseptics.
- 15.2 Wound dressings.
- 15.3 Desloughing agents.

16. Mammary Gland

- 16.1 Intra-mammary preparations.
- 16.2 Preparations for the care of teats and udders.

17. Antimicrobials

- 17.1 Antibacterials.
 - 17.1.1 Beta-lactams.
 - 17.1.1.1 Penicillins.
 - 17.1.1.2 Cephalosporins.
 - 17.1.2 Tetracyclines.
 - 17.1.3 Aminoglycosides.
 - 17.1.4 Macrolides and Lincosamides.
 - 17.1.5 Amphenicol.
 - 17.1.6 Quinolones.

- 17.1.7 Sulphonamides and potentiators.
- 17.1.8 Nitrofurans.
- 17.1.9 Polypeptides.
- 17.1.10 Other.
- 17.1.11 Antibacterial combinations.
- 17.2 Antifungals.
- 17.3 Antivirals.
- 17.4 Anti-protozoals.
 - 17.4.1 Anticoccidials.
 - 17.4.2 Antibabesials.
 - 17.4.3 Spirochaeticides.
 - 17.4.4 Others.

18. Antiparasitic Agents

- 18.1 Endoparasiticides.
 - 18.1.1 Benzimidazoles and Probenzimidazoles.
 - 18.1.2 Macrocyclic lactones.
 - 18.1.3 Halogenated salicylanilides and Nitrophenols.
 - 18.1.4 Imidazoles.
 - 18.1.5 Tetrahydropyrimidines.
 - 18.1.6 Piperazines.
 - 18.1.7 Organophosphores.
 - 18.1.9 Combinations.
- 18.2 Endectocides.
- 18.3 Ectoparasiticides.
 - 18.3.1 Organochlorines.
 - 18.3.2 Organophosphores.
 - 18.3.3 Pyrethrin and Pyrethroids.
 - 18.3.4 Formamidines.
 - 18.3.5 Nitroquanidines.
 - 18.3.6 Phenylpyrazoles.
 - 18.3.7 Insect growth hormones.
 - 18.3.8 Chitin inhibitors.
 - 18.3.9 Others.
 - 18.3.10 Combinations.

19. Vitamins, Minerals And Geriatric Preparations

- 19.1 Vitamins only.
- 19.2 Vitamin and mineral combinations.
- 19.3 Minerals and electrolytes.
- 19.4 Vitamins, electrolytes and aminoacid combinations.

20. Cytostatic Agents**21. Immune Modulating Agents****22. Chelating Agents****23. Contrast Media****24. Biologicals**

- 24.1 Dogs vaccines.
- 24.2 Cats vaccines.
- 24.3 Poultry vaccines.
- 24.4 Other vaccines.
- 24.5 Other biologicals.

25. Production Enhancers

- 25.1 Antimicrobials.
- 25.2 Sex Hormones.
- 25.3 Beta agonists.
- 25.4 Other.

26. Fish and aquatic species Medicines**27. Feed additives****28. Veterinary Complementary Medicines: Discipline-Specific Traditional Claims**

- 28.1 Aromatherapy

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Annexure 3

Certificate of registration for medicines

MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT NO. 101 OF 1965): MEDICINE REGISTRATION CERTIFICATE

It is hereby certified that registration of the medicine described below has been approved by the Authority in terms of section 15(3)(a) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), subject to the conditions indicated.

1. Proprietary name.....
2. Registration number.....
3. Approved name of every active pharmaceutical ingredient and quantities thereof per dosage unit or per suitable mass or volume or unit of the medicine.....
4. Dosage form.....
5. Conditions under which the medicine is registered.....
6. Name of holder of certificate of registration.....
7. Name and address of the manufacturer and the manufacturing facility.....
8. Name of the final product release control.....
9. Name of the final product release responsibility.....
10. Date of registration.....
11. Category of medicine.....
12. Class of the medicine.....
13. Discipline of medicine, if falling under Category D.....

Chief Executive Officer

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