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

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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 315 **22 April 2014**

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

GENERAL REGULATIONS RELATING TO MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES (IVDs)

The Minister of Health, in consultation with the Medicines Control Council, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), intends to make the regulations in the Schedule.

Interested persons are invited to submit, within three months of publication of this notice, comments on the proposed regulations to the Department of Health, for the attention of the Registrar: Medicines Control Council, Private Bag X828, Pretoria, 0001.

SCHEDULES

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DEFINITIONS

1. In these Regulations any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and unless the context otherwise indicates-

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

"accessory" to a medical device means an article intended specifically by its manufacturer to be used together with that medical device to enable that device to be used in accordance with its intended use;

"active medical device" means any medical device of which the operation depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this to energy but excluding medical devices intended to transmit energy, substances or other elements between an active medical device and the user, without any significant change in the energy, substance or other element being transmitted;

"active device for diagnosis" means any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

"active implantable medical device" means a medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

"adverse event" in relation to a medical device or IVD means possible faults or failures of the medical device or IVD, difficulties in the use of or an undesirable outcome associated with the use of the medical device or IVD that can or does result in permanent impairment, injury or death to the professional user or patient user;

"applicant" means a person, being a resident of the Republic of South Africa who submits an application for the registration of a medical device or IVD, or an update or amendment to an existing registration;

"as determined by Council" means as determined by Council in the guidelines as published in the Gazette from time to time;

"authorised prescriber" means any person authorised by the Act to prescribe any medical device or IVD;

"authorised representative" means any natural person, resident in the Republic of South Africa, who has the written mandate to represent a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic and to act on his or her behalf for specified tasks with regard to the latter's obligations and who has submitted an application for the registration of a medical device or IVD and in whose name the manufacturer licence, wholesaler licence and or certificate of registration is issued. The authorised representative is responsible for all aspects of the medical device or IVD, including quality, safety and compliance with conditions of registration;

"batch number" or **"lot number"** means a unique number or combination of numbers or cyphers allocated to a lot or a batch by the manufacturer;

"body orifice" means any natural opening in the body as well as the external surface of the eyeball or any permanent artificial opening such as a stoma or permanent tracheotomy;

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

"central circulatory system" means the major internal blood vessels including the following: pulmonary veins, pulmonary arteries, cardiac veins, coronary arteries, carotid arteries (common, internal and external), cerebral arteries, brachiocephalic artery, aorta (includes all segments of the aorta), inferior and superior vena cava and common iliac arteries;

"clinical investigation" means a study in respect of a medical device or IVD for use in humans and animals that involves human or animal subjects and that is intended to discover or verify the safety or performance of the medical device or IVD;

"combination device" means a medical device incorporating as an integral part, a substance which if used separately, can be considered to be a medicine and which is liable to act on the human body with action ancillary to that of the medical device;

"conformity assessment" means the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Council, to determine that a medical device is safe and performs as intended by

the manufacturer and, conforms to the Essential Principles of Safety and Performance for Medical Devices;

"conformity assessment certificate" means the certificate used to demonstrate that a manufacturer has been assessed and has the appropriate systems in place to manufacture the device;

"continuous use" in terms of medical devices or IVDs means -

(a) the entire duration of use of the medical device or IVD without regard to temporary interruption of use during a procedure, or temporary removal for purposes such as cleaning or disinfection of the medical device or IVD;

(b) the accumulated use of a medical device or IVD that is intended by the manufacturer to be replaced immediately with another of the same type;

"custom made medical device" means any medical device specifically made in accordance with a written prescription or order given by a person authorised for the same by virtue of professional qualifications and in accordance with specific design characteristics and is intended for the sole use of a particular user and excludes mass produced medical devices which only need adaptation to meet the specific requirements of the health professional user;

"declaration of conformity" means the procedure whereby the manufacturer ensures and declares that the application of the quality system approved for the design, manufacture and final inspection of the products concerned as required by Council, which are subject to audit and surveillance, are fulfilled;

"essential principles" set out the requirements relating to the safety and performance characteristics of medical devices and IVDs as approved by Council;

"expiry date" means the date up to which a medical device or IVD will retain the properties which are mentioned on the label which properties can change after the lapse of time and after which date the medical device or IVD shall not be sold to the public or used;

"family" means a medical device comprising of the same type of device available in different models and sizes;

"group" means a medical device or IVD comprising a collection of medical devices or IVDs such as a procedure pack or procedure tray or system or procedure kit, that are packaged together for a specific intended purpose and sold under a single name;

"holder of a certificate of registration" (HCR) means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medical device or IVD, including quality and safety and compliance with conditions of registration;

"implantable device" means any device, including those that are partially or wholly absorbed, which is intended to be totally introduced into the human body or, to replace an epithelial surface or the surface of the eye by surgical intervention which is intended to remain in place after the procedure, for at least 60 minutes;

"intended purpose" means the objective intended use or purpose as the case may be, for which the medical device or IVD is intended according to the data supplied by the manufacturer or authorised representative on the labelling, in the instructions and in the promotional materials;

"invasive device" means a device which, in whole or in part, penetrates inside the body either through a body orifice or through the surface of the body;

"lay person" means an individual that does not have formal training in a relevant field or discipline;

"manufacture" means all operations including the design, purchasing of material, specification development, production, fabrication, assembly, processing, releasing, packaging, repackaging, and labelling of a medical device or IVD as the case may be, including putting a collection of medical devices or IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls;

"manufacturer" means –

(a) the natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD before it is placed on the market under the natural or legal person's own name, or in the name of a firm

or company, regardless of whether these operations are carried out by that person by himself or on his behalf by a third party; or

(b) any other person who assembles, packages, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device or IVD with a view to their being placed on the market under the natural or legal person's own name, apart from a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients;

"manufacturer's evidence" is the substantive evidence of the manufacturer's quality system, that demonstrates that the manufacturer has appropriate manufacturing processes in place to manufacture the device(s);

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

"modification" in terms of a medical device or IVD means any significant change in the medical device or IVD or any change in the purpose thereof where significant change may include the manufacturing process, facility or equipment, the quality control measures used to control the quality and sterility of the medical device or IVD or of the materials used in manufacture, the design of the medical device or IVD, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories and the intended use of the medical device or IVD including any new or extended use, any addition or deletion of a contra-indication of the medical device or IVD and any change to the period used to establish its expiry date;

"near patient testing" means testing performed outside a laboratory environment by a healthcare professional not necessarily a laboratory professional, generally near to, or at the side of, the patient;

"Conformity Assessment Body" means a body corporate or other legal entity, locally or internationally, accredited by the Council as competent to carry out the assessment, verification and certification of medical devices or IVDs before they are placed on the market by manufacturers;

"nomenclature" means the common generic description as per the Global Medical Device Nomenclature for medical devices having similar features, characteristics and intended use;

"parallel importation" means the importation into the Republic of a medical device or IVD protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of such patent holder;

"parallel importer" means a person who parallel imports a medical device into the Republic on the Council of a permit issued in terms of regulation 5(3);

"person" means both a natural and a juristic person;

"professional use only medical devices" means a medical device that is to be used on an individual solely by or under the supervision of a qualified medical practitioner;

"radiation" means energy in the form of electromagnetic waves or acoustical waves;

"radiation-emitting device" means any device that is capable of producing and emitting radiation and any component of, or accessory to, such a device;

"refurbished medical device" means a medical device the whole or any part of which has been substantially rebuilt, re-equipped or restored, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the original owner of the original medical device, and without prejudice to the generality of the foregoing, a refurbishment of a medical device may involve any or all of the following actions including , but are not limited to, repair, rework, update of software / hardware and replacement of worn parts with parts approved for use by the original manufacturer, performed in a manner consistent with product specifications and service procedures defined by the original manufacturer for that type of equipment without significantly changing the finished equipment's performance, safety specifications and/or intended use as defined in its original registration;

"self-testing" means testing performed by lay persons;

"single use device" means medical device or IVD that is intended to be used on an individual user during a single procedure and then disposed of and which is not intended to be reprocessed and used again;

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

"surgically invasive device" means an invasive device which penetrates inside the body through the surface of the body with the aid of, or in the context of, a surgical operation and includes devices and which produce penetration other than through an established body orifice;

"trademark" means a trademark as defined under section 2 of the Trade Marks Act, 1993 (Act No. 194 of 1993);

"test kit" means an *in vitro* diagnostic device that is a packaged system of the principal or key components of an analytical method used to determine the presence of a specific analyte(s) in a given matrix (es);

"unique device identification" (UDI) means the combination of words, numbers, symbols, or letters assigned by the manufacturer to uniquely identify the device and any of its variants;

"user" means the person or organisation that uses a medical device or IVD;

"wholesaler" means a dealer who purchases medical devices or IVDs from a manufacturer and sells them to a retailer and includes a wholesale pharmacy.

THE MANNER AND CONDITIONS FOR ALLOWING INTERNATIONAL TENDERING

2 (1) The State may tender for a medical device or IVD internationally if such a medical device or IVD -

a. can be obtained at a lower price outside of the Republic; or

b. is, in the opinion of the Minister, essential for national health.

(2) A medical device or IVD referred to in subregulation (1), which at the time of request for tenders is not registered, may be subjected to an expedited registration process in terms of regulation 3.

(3) A medical device or IVD cannot be procured by international tender unless such medical device or IVD is registered in terms of the Act.

EXPEDITED REGISTRATION FOR MEDICAL DEVICES OR IVDS

3. (1) The Minister may approve, upon written application, an expedited registration for medical devices or IVDs in short supply or where there is no supply, when considered by the Minister as in the national interest.

(2) The applicant shall be notified by the Council within 30 days of the date of receipt of the application whether or not the application is to be subjected to expedited registration process.

(3) The Council may request any information with respect to an application under consideration and such information shall be furnished by the applicant within a period indicated by the Council, failing which the Council may reject an application.

(4) The Council shall, within nine months from the date of receipt of the application by the registrar, make a decision with regard to the application and inform the applicant of such decision.

(5) Notwithstanding the above subregulations, an application for an expedited registration process must still comply with regulation 11.

PARTICULARS TO BE PUBLISHED IN THE GAZETTE

4. The following particulars with regard to applications for registration referred to in section 15(11) shall be published in the Gazette:

a. The name of the medical device or IVD;
b. the name of the applicant who registered the application;

c. the number allocated to it in terms of section 15 of the Act;
d. the name and address of the manufacturer and manufacturing facilities;
e. the class of medical device or IVD; and
f. the nomenclature system or code of the medical device or IVD.

IMPORTATION OF MEDICAL DEVICES OR IVDS IN TERMS OF SECTION 15C

5. (1) A medical device or IVD referred to section in 15C(b) of the Act may be sold if:

a. the medical device or IVD is being sold outside the Republic with the consent of the holder of the patent of such medical device or IVD;
b. the medical device or IVD is imported from a person licenced by a regulatory Council recognised by the Council;
c. the person desiring to import such medical device or IVD is in possession of a permit issued by the Minister; and
d. the medical device or IVD is registered in terms of the Act.

(2) A person desiring to import a medical device or IVD referred to in subregulation (1) must submit to the Minister:

a. a duly completed application on a form approved and provided by the Minister;
b. a certified copy of his or her identity document or in the case of a juristic person, a certificate of registration as such in the Republic;
c. a certified copy of his, her or its registration in terms of the Pharmacy Act, 1974, where applicable;
d. a certified copy of a licence in respect of premises in terms of section 19 of Customs and Excise Act, 1964 (Act No. 91 of 1964);
e. documentary proof-

i. that the medical device or IVD is under patent in the Republic;
ii. that the medical device or IVD is registered in its country of export by a regulatory Council recognised by the Council;
iii. regarding the lowest price at which the medical device or IVD is sold in the Republic;

iv. regarding the price at which the medical device or IVD will be sold in the Republic;

v. that he, she or it is able to comply with good manufacturing and/or distribution practices as determined by the Council; and

f. an undertaking that he, she or it will ensure the continued safety, quality and performance of the medical device or IVD.

(3) The Minister-

a. may approve the application referred to in subregulation (2) with or without conditions;

b. must if he or she approves the application, issue the applicant with a permit, which is valid for a period of two years;

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 Minister.

(5) A person issued with a permit in terms of subregulation (3) must apply to the Council for the registration of the medical device or IVD specified in the permit by submitting to the Registrar.

a. a certified copy of that permit;

b. a duly completed application form approved and provided by the Council; and

c. an application fee as determined by the Council.

(6) The Council

a. must, if satisfied that the application referred to in subregulation (5) complies with the requirements of the Act and these regulations and those of the Council regarding the safety, quality and performance of the medical device or IVD, 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 medical device or IVD under the name approved by the Council.

(7) The certificate of registration referred to in subregulation (6) may only be transferred with the approval of the Council.

(8) A person importing a medical device or IVD in terms of this regulation shall in writing inform –

a. the Minister of any change of facts in relation to the application for a permit issued in terms of subregulation (5) or conditions under which such permit was issued;
b. the Council of any amendments to the application for the registration of medical devices or IVDs or the conditions for the registration of such medical device or IVD;
c. the holder of a certificate of registration in the Republic of the registration of the medical device or IVD in terms of this regulation.

(9) A medical device or IVD registered in terms of this regulation may only be sold to the State or a person authorised to sell medical devices or IVDs in terms of the Act or any other legislation.

IMPORTATION OF MEDICAL DEVICES AND IVDs INTO THE REPUBLIC

6. (1) No person shall import any medical device or IVD, including medical devices or IVDs imported in terms of section 15C of the Act, read together with regulation 5, into the Republic except through one of the following ports of entry:

a. Cape Town Airport or harbour;
b. Port Elizabeth Airport or harbour;
c. King Shaka International Airport or Durban harbour; and
d. OR Thambo International Airport

(2) A person may only import a medical device or IVD if such person:

a. is licensed in terms of the Act to import medical devices or IVDs; and
b. in the case of unregistered medical devices or IVDs, is authorised by the Council to import such unregistered medical devices or IVDs.

TRANSMISSION OF MEDICAL DEVICES OR IVDs THROUGH THE REPUBLIC

7. (1) Medical devices and IVDs that are transmitted through the Republic shall-

a. while in the Republic be stored in a bonded warehouse which is registered with the Council; and
b. not be manipulated while in the bonded warehouse unless authorised by the Council.

(2) A bonded warehouse referred to in subregulation (1) must comply with good storage conditions as determined by the Council.

LICENCE TO MANUFACTURE, IMPORT, EXPORT OR ACT AS A WHOLESALER OR DISTRIBUTOR OF MEDICAL DEVICES OR IVDs

8. (1) A person referred to in section 22C(1)(b) of the Act-

a. must prior to commencing business as such-

i apply to the Council for a manufacturer licence to manufacture, import or export medical devices or IVDs or a wholesale licence to act as wholesaler or distribute medical devices or IVDs;
ii appoint, and designate as such an authorised representative who will control the manufacturing and or distribution of medical devices or IVDs;
iii appoint and designate a natural person who resides in the Republic, who shall be responsible to the Council for compliance with the Act;

b. must submit to the Registrar an application, on a form approved and provided by the Council, for a licence as contemplated in sub-regulation (1) (a) (i);

c. must as part of the application in sub-regulation (1)(b) provide acceptable documentary proof of:

i. the particulars of the owner of the business;

ii. the particulars of the authorised representative;

iii. registration of a pharmacist where applicable;

iv. qualifications of staff to manufacture, store, distribute, sell, maintain or repair medical devices or IVDs in terms of the Act;

vi. the ability to comply with good manufacturing or distribution practices as determined by the Council, 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 conducted, 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;

ee. a manual of procedures and practices to be implemented to ensure the safety, quality and performance of medical devices or IVDs to be manufactured or distributed and sold; including a procedure for recording all entities to whom a medical device or IVD has been distributed, or in the case of a wholesaler or distributor, the record of the entity that has supplied them with the medical device or IVD. The procedure should include a requirement that such records be maintained for a period of at least five years after the distribution of the last medical device or IVD of a kind.

d. must specify the medical devices or IVDs or group or family of medical devices or IVDs to be manufactured, imported, exported or distributed and sold;

e. must pay the application and inspection fees as determined by the Council.

(2) The Registrar may give the person referred to in sub-regulation (1) written notice to furnish the Council with such additional documentation or information as the Council may require, within a reasonable time, specified in the notice.

(3) The Council must where applicable, inspect the business premises specified in the application.

(4) If the Council is satisfied that:

a. the person referred to in subregulation (1) complies with the prescribed requirements;
b. the application for a licence to manufacture, import, export or act as wholesaler of medical devices or IVDs complies with the prescribed requirements;
c. the applicant is able to comply with good manufacturing or distribution practices, then the Council must approve, with or without conditions, the application and issue such person with a licence.

(5) The Registrar must:

a. keep a separate register for each of the categories of licensees referred to in sub-regulation (1)(a)(i); and
b. enter the licence number, the name of the licensee and his or her physical and postal addresses, in such register.

(6) Notwithstanding the period of validity of the licence the licensee shall pay the annual fee for continued registration as determined by the Council.

(7) A licensee must notify the Registrar in writing of any change to any of the particulars furnished in the application or entered in the register, which occurs after the issue of the licence.

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

(9) A person in respect of whose entry a removal as contemplated in sub-regulation (8) has been made, must be notified of such removal and any certificate issued in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

(10) The Council may direct the Registrar to remove from the register the name of the licensee-

a. who does not comply with the Act or the conditions of a licence;
b. if the authorised representative fails to control the manufacturing or distribution of medical devices or IVDs and the licensee has failed to furnish written reasons within 21 days after the date upon which a notice is given of the Council's intention to remove the name of the licensee from the relevant register and to close such business why the licensee's name should not be removed or the business should not be closed: Provided that if the Council is of the opinion that it is in the interest of the public, it may dispense with the required notice.

PERIOD OF VALIDITY OF A LICENSE ISSUED IN TERMS OF REGULATION 8 AND RENEWAL OF LICENCES

9. (1) A licence issued in terms of regulation 8 shall be valid for a period of 5 years from the date of issue.

(2) A licence referred to in sub-regulation (1) which has expired may be renewed by application to the Council.

(3) An application referred to in sub-regulation (2) shall –

a. contain at least the information or documentation referred to in regulation 8(1)(c), as the case may be;
b. be accompanied by a prescribed fee; and
c. be made at least 90 days before the expiry of the existing licence.

APPEAL AGAINST THE DECISION OF THE COUNCIL

10. (1) An appeal to be lodged or representations to be made in terms of Section 24 of the Act against a decision of the Council, shall be lodged or made within 30 days from the date on which the decision appealed against or in respect of which representations are made was communicated to the appellant or person making representations.

(2) In lodging the appeal or making representations, the appellant or person making representations shall send a notice by registered mail to the Minister, for attention the Registrar, Medicines Control Council, Private Bag X828, Pretoria, 0001, or

(3) The notice referred to in sub-regulation (2) shall set out clearly and succinctly the basis for the appeal or representations.

(4) The Minister shall within 30 days of receipt of notice of appeal, appoint an appeal committee to decide the appeal.

(5) 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 document; and

d. 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 Council;

ii. administer an oath to or accept an affirmation from any person called as a witness at the appeal.

(6) Persons appearing before the Appeal Committee may be represented by a legal practitioner.

(7) The appeal committee shall consider the appeal and make a decision in regard thereto within a period of 30 days from the date –

a. on which it was appointed; or,
b. when the appeal hearing was completed, whichever is the later.

APPLICATION FOR REGISTRATION OF A MEDICAL DEVICE OR IVD

11. (1) Any person residing and doing business in the Republic may make an application for the registration of a medical device or IVD.

(2) The application referred to subregulation (1) shall include the particulars of the natural person with appropriate knowledge of all aspects of the medical device or IVD who shall be responsible for communication with the Council.

(3) An application referred to in subregulation (1) shall be made on the appropriate form obtainable from the Registrar and shall be accompanied by:

a. a properly completed screening form obtainable from the Registrar;
b. a proposed label for use on the medical device or IVD, if applicable;
c. where applicable,

i. a copy of the manufacturer licence together with the current Good Manufacturing Practice certificate from the regulatory authority from the country of origin of the medical device or IVD, as the case may be;
ii. a certified copy of the conformity assessment certificate issued by the notified body that the Council approves of; and

iii. a certified copy of the manufacturer's evidence in support of conformity to the *Essential Principles* issued by the original manufacturer;

d. data on the safety, performance and quality of the medical device or IVD whether positive or negative as may determined by the Council

e. proof of the existence of a manufacturing site, i.e. a Site Master File and/or the manufacturer's Quality Manual;

f. any other information as the Council may determine; and

g. the application fee.

(4) All information referred to in sub-regulation (3) shall be at least in English.

(5) The application form referred to in sub-regulation (3) shall contain at least the following information:

a. Particulars of the Applicant and the prospective holder of the certificate of registration:

i. Name;

ii. Business Address;

iii. Postal Address;

iv. Telephone Number;

v. Fax Number;

vi. e-mail address; and

vii. Contact details of the person referred to in sub-regulation (2) in the case of a juristic person.

b. particulars of the device or IVD:

i. name, make and model where applicable;

ii. intended purpose;

iii. country of origin and registration status outside the Republic;

iv. classification in all countries where registered and proposed classification in South Africa;

v. nomenclature system code;

vi. in the case of a combination medical device the approved name and proposed schedule of the therapeutic substance;

vii. name and address of the manufacturer(s); and

viii. name and address of the clinical investigation site(s), where applicable.

(6) A medical device or IVD in respect of which an application for registration is made must comply with the Essential Principles for Safety and Performance of Medical Devices which include requirements for quality, safety and performance, as determined by the Council.

(7) An application must be made in respect of each individual medical device or IVD, or medical device or IVD group or family.

(8) In an instance where a medical device or IVD in respect of which an application is made or was registered with any regulatory body outside the Republic, the following information in respect of such medical device or IVD must accompany the application:

a. a copy of certificate of registration where applicable;
b. package insert or instructions for use where applicable ;
c. conditions of registration; and
d. any other information as determined by the Council.

INFORMATION THAT MUST APPEAR IN THE REGISTER FOR MEDICAL DEVICES OR IVDs

12. The medical device or IVD register must, in respect of any registered medical device or IVD contain the following information:

a. the name, make and model, where applicable of the medical device or IVD;
b. the registration number allocated to the medical device or IVD;
c. in the case of a combination medical device the approved name of each active ingredient of the medical device and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medical device;
d. the intended purpose of the medical device or IVD;
e. the name of the applicant or the holder of the certificate of registration;

f. the name and address of the manufacturer(s) and the manufacturing facilities;
g. the date of registration of the medical device or IVD;
h. the conditions of registration of the medical device or IVD determined in terms of section 15(7) of the Act;
i. the class of medical device or IVD; and
j. the nomenclature system code allocated to the medical device or IVD.

AMENDMENT TO THE MEDICAL DEVICE AND IVD REGISTER

13. (1) A holder of a certificate of registration may submit to the Registrar an application on a form as determined by the Council to amend an entry made into the medical devices or IVDs register with regard to a particular medical device or IVD.

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

a. the registration number of the medical device or IVD;
b. the name and business address of the applicant;
c. declaration by the applicant that the information furnished is complete and accurate;
d. the details of the amendment applied for;
e. the manufacturer licence number of the manufacturer; and
f. any other information as determined by the Council.

CLASSIFICATIONS OF MEDICAL DEVICES AND IVDs

14. (1) The following are the classes of medical devices and IVDs –

(a) Class A - Low Risk
(b) Class B - Low-moderate Risk
(c) Class C - Moderate-high Risk
(d) Class D - High Risk

where risk relates to the patient or to public health.

(2) All medical devices, except custom made devices, and all IVDs shall be registered with the Council in terms of such call up notices before they may be sold or used in the Republic.

(3) The classification of medical devices and IVDs shall be as determined by Council in accordance with the technical rules published in the Gazette.

(4) Where the classification of a medical device or IVD is inconclusive and places it in more than one class or between classes after following the technical rules the Council will place it in the higher of the risk classes.

(5) The Council shall consider the classification of a medical device or IVD individually taking into account its design and intended use.

REGISTRATION CERTIFICATE

15. A certificate of registration substantially in the form shown below shall be issued by the Registrar in terms of section 15(4) after a medical device or IVD has been registered:

MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT 101 OF 1965)
MEDICAL DEVICE OR IVD REGISTRATION CERTIFICATE

It is hereby certified that registration of the medical device or IVD described below has been approved by the Council in terms of Section 15(4) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), subject to the conditions indicated.

1. Name .....
2. Registration number .....
3. Class of medical device or IVD .....
4. In the case of combination medical devices the approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume or unit of the medical device or reagent of an IVD as the case may be .....
5. Nomenclature system or code .....
6. Conditions under which the medical device or IVD is registered .....
7. Registered in the name of (holder of certificate of registration) .....
8. Name and address of the manufacturer and the manufacturing facility .....
9. Date of registration .....

.....

Registrar

Issued at ..... on ..... 20 .....

DESTRUCTION OF MEDICAL DEVICES OR IVDs

16. (1) No medical devices or IVDs may be disposed of into municipal sewerage systems.

(2) The destruction or disposal of medical devices or IVDs must be conducted in such a manner as determined by the Council to ensure that they are not retrievable or cannot be reused or reassembled.

PARTICULARS FOR A PRESCRIPTION OR ORDER FOR A MEDICAL DEVICE

17. (1) Any combination medical device containing a medicine, requiring a prescription, where applicable, must be written in legible print, typewritten or computer generated and signed in person by a medical practitioner, dentist, veterinarian or authorised prescriber or in the case of an order for a medical device, an authorised person, and must at least state the following:

a. the name, qualification, practice number and address of the prescriber or authorised person placing the order;
b. the name and address of the patient in the case of a prescription or the name and address of the person to whom the medical device is delivered in the case of a prescription issued by a veterinarian;
c. the date of issue of the prescription or order;
d. the name of the medical device(s); and
e. the number of times the prescription or order may be repeated.

(2) In the case of a faxed, e-mailed, telephone or electronic transmission by other means of a prescription for a combination medical device containing a medicine or order the pharmacist or a responsible person must verify the authenticity of the prescription or order.

(3) A permanent copy of the faxed, e-mailed, telephone or other electronic transmitted prescription or order referred to in sub-regulation (2) must be made for record purposes.

(4) The faxed, e-mailed, telephone or other electronic transmitted prescription or order should be followed by the original prescription or order within 7 working days.

(5) In the case of a prescription for a custom made combination medical device the specific design characteristics for a particular user must be included.

(6) A record of the lot number, or if applicable, the UDI of a distributed medical device or IVD must be maintained by the pharmacist or a responsible person.

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

18. (1) No person shall import, export, sell by wholesale, produce, or manufacture or use in the manufacture of any medical device or IVD any substance referred to in section 22A(12) of the Act unless the Council is supplied with a return reflecting the following information on or before 28 February of each year-

a. the quantity of such substance, as a raw material or as contained in a medical device or IVD 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 when contained in a medical device or IVD;
c. the quantity of such substance contained in a medical device or IVD, which were disposed of during the preceding calendar year through –

i exportation; or
ii destruction thereof;

e. the quantity of such medical device or IVD containing such substance remaining in stock on 31 December of the preceding year.

(2) Notwithstanding sub-regulation (1), the Council 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 sub-regulation (1) must comply with the following requirements:

a. all quantities must be expressed in metric units as a percentage base of the relevant substance;
b. in the case of medical devices or IVDs containing opium, quantities must be expressed in terms of opium containing 10% of anhydrous morphine;
c. medical devices or IVDs containing preparations obtained not directly from opium itself but by mixing opium alkaloids must be expressed in terms of morphine; and
d. where stocks are held or manufacture has been undertaken on behalf of another applicant, this fact must be indicated.

REGISTER OF SPECIFIED SCHEDULE 5, SCHEDULES 5 OR 6 MEDICINES SUBSTANCES

19. (1) A person importing, exporting, manufacturing or selling medical devices or IVDs containing specified Schedule 5 or Schedule 6 substances shall keep a register of such medical devices or IVDs.

(2) The register referred to in sub-regulation (1) must indicate the quantity of every such medical device or IVD remaining in stock on the last day of March, June, September and December of each year and must also contain the following information:

a. the date on which the medical device or IVD was received or supplied;
b. the name, business address of the person from whom the medical device or IVD was received or sent and in the case of an imported medical device or IVD, the import permit number;
c. the name and address of the person who purchased the medical device or IVD;
d. the quantity in words and figures of such medical device or IVD;
e. in the case of the supply of the medical device or IVD 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 shall be recorded;

f. the quantity of the substance used during the manufacturing process of a medical device or IVD; and

g. any other information as the Council may determine.

(3) The register referred to in sub-regulation (1) must 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 by computer, a computer printout must be made monthly, dated, signed and filed.

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

METHOD OF TAKING SAMPLES DURING AN INVESTIGATION, THE CERTIFICATE TO BE ISSUED AND THE REPORTING OF ANALYSIS RESULTS

20. (1) An inspector may, in terms of the Act, take a sample, or any quantity of samples, of a medical device or IVD for purposes of testing, examination or analysis by a person designated as an analyst, engineer, pharmacologist or pathologist

(2) The sample or samples contemplated in subregulation (1) must –

a. be taken in the presence of the person who is in charge of such medical device or IVD, or in the absence of such person, in the presence of any witness present;

b. be taken and stored in such a manner as to ensure its integrity during the entire examination process of the sample;

c. be packed and sealed and suitably labelled or marked in such a manner as its nature may permit and must be transmitted by any suitable means to an analyst, engineer, pharmacologist or pathologist together with the certificate signed by the inspector, a copy of which must be issued to the person contemplated in paragraph (a) by the inspector at the earliest possible time.

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

(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 Council may require any holder of a certification of registration to supply the Council with a sample of a particular medical device or IVD in order to test, examine or analyse such sample.

(6) Certificates or reports issued in terms of this regulation must be submitted to the Registrar within 7 days from the date of issue.

SEIZURE OF MEDICAL DEVICES OR IVDs

21. (1) A medical device or IVD may be seized if it-

a. is unregistered and sold in contravention of the Act;
b. is suspected counterfeit;
c. is misbranded;
d. has expired;
e. is suspected stolen;
f. is Scheduled and is possessed by an unauthorised person or by an authorised person but in unauthorised quantities;
g. has been declared undesirable in terms of the Act;
h. belongs to the State and is found possessed by an unauthorised person; or
i. is used in unauthorised clinical trial or investigation.

(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 section 28 (1) (c) of the Act 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) shall make a written inventory of all samples taken which 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;
c. the personal details of the person in whose presence the samples were taken; and
d. the name of the inspector taking the sample.

(5) An inspector may:

a. seal or disable, as the case may be, any medical device or IVD to prevent its further use;
b. remove seized medical devices or IVDs to a secure place designated by the Council pending the outcome of any investigation; and
c. condemn seized medical devices or IVDs for permanent destruction and disposal after a due investigation was conducted by the Council.

(6) No person may, without the permission of the Council, continue to use, destroy, remove, cause or permit to be removed, any medical device or IVD that has been seized and placed under an embargo.

(7) The Council shall safely dispose of any condemned seized medical devices or IVDs in accordance with regulation 16.

(8) The Council shall recover the cost of removal, storage or disposal of any medical device or IVD that was seized from the licence holder or applicant.

CONDUCT OF CLINICAL TRIALS AND INVESTIGATIONS

22. (1) A person desiring to initiate or conduct a clinical trial or investigation in respect of an unregistered medical device or performance assessment for an IVD, or a new intended purpose of a registered medical device or IVD, shall apply to the Council on a form determined by the Council for authorization to conduct such a clinical trial or investigation.

(2) An application referred to in sub-regulation (1) shall be accompanied by a fee as determined in the Regulations relating to fees payable to the Council and shall contain at least the following information:

a. investigation or trial protocol;
b. investigator's brochure containing relevant pre-clinical, mechanical, electrical and radiation data and where applicable, human or animal clinical data with the medical device or IVD concerned;
c. Curriculum Vitae of all investigators;
d. signed declaration by the applicant and all investigators that they are familiar with and understand the protocol and will comply with Good Clinical Practice as determined by the Council in the conduct of the trial;
e. informed consent document and endorsement by any ethics committee recognised by the Council; and
f. name and address of the institution where the clinical trial or investigation will be conducted.

(3) The clinical investigation or trial protocol referred to in paragraph (a) of sub-regulation (2) shall contain at least the following information:

a. number of human or animal subjects to be involved in the investigation of trial;
b. the name of an investigator who shall be an appropriately qualified and competent person approved by the Council, resident in the Republic, and must be in charge of the site where trials are conducted;
c. quantity of the investigational medical device or IVD units to be used in the trial;

d. information in respect of the design, manufacture and expected performance of the medical device or IVD; and
e. any other information as determined by the Council.

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

(5) No person shall conduct clinical investigations or trials referred to in subregulation (1) without the authorisation of the Council.

(6) The person conducting the clinical investigation or trial must:
a. submit progress reports to the Council after every six months from the date when the clinical investigation or trial was started and 30 days after the completion or termination of the clinical investigation or trial;
b. submit adverse event reports immediately or as soon as practically possible to the Council;

(7) The Council may request additional information, inspect a clinical investigation or trial or withdraw the authorisation to conduct a clinical investigation or trial if the Council is of the opinion that the safety of the subjects of the investigation or trial is compromised, or that the scientific reasons for conducting the investigation or trial have changed.

(8) A medical device or IVD referred to in sub regulation (1) must be properly labelled and the package must sufficiently identify the-

a. clinical investigation or trial to be carried out;
b. medical device or IVD to be used for the conduct of the clinical investigation or trial;
c. persons or animal species on whom the medical device or IVD is to be used; and
d. name(s) and address(es) of the premises where the clinical investigation or trial is to be carried out.

(9) Any authorisation for the conduct of a clinical investigation or trial by the Council may be made subject to such conditions as determined by the Council.

SKILLS OF MEMBERS OF THE COUNCIL AND ITS COMMITTEES

23. (1) The Council shall include at least one biomedical engineer, one clinical engineer, one general surgeon, one cardiovascular surgeon and one orthopaedic surgeon who by qualification and experience have the necessary general and specialist surgical, clinical and biomedical knowledge and skills.

(2) The Council shall appoint a medical device committee to investigate and report to the Council and which shall have at least a medical practitioner, a surgeon and a biomedical engineer with clinical, surgical and engineering skills amongst its members. The committee shall include but not be limited to medical practitioners, surgeons and engineers with expertise in the specialised field of the specific medical device or IVD being evaluated.

ADVERSE EVENTS REPORTING

24. (1) The applicant or holder of a certificate of registration in respect of a medical device or IVD shall inform the Council, in the manner and within the time frame as determined by the Council, of suspected adverse events reported to him, her or it occurring as a result of the use of such a medical device or IVD.

(2) Sub-regulation (1) also applies in the case of unregistered medical devices or IVDs used in terms of sections 14(4), 15C and 21 of the Act.

(3) The holder of the certificate referred to in sub-regulation (1) or the applicant with regard to medical devices or IVDs referred to in sub-regulation (2), as the case may be, shall-

a. within the time frame determined by the Council after receipt of the report referred to in sub-regulation (1) inform the Council of the steps to be taken to address the adverse events;

b. whenever requested by the Council, conduct a concise critical analysis of the safety and performance of the medical device or IVD and submit the results thereof to the Council within a specified time frame; and

c. in the case where, after receipt of the results referred to in paragraph (b), the Council determines that the medical device or IVD may not be safe to use, submit, if required to do so to the Council –

i case reports of all suspected adverse events in respect of the medical device or IVD; and

ii where applicable other data such as medical device or IVD usage figures, periodic safety update reports, performance studies, etc;

c. Keep and maintain or have access to records of all adverse event data in respect of his, her or its medical devices or IVDs.

(4) Nothing in this regulation shall be interpreted as prohibiting any person from reporting any adverse event to the Council.

(5) Notwithstanding the provisions of sub regulation (1) or (4) any dentist, medical practitioner, pharmacist, nurse, authorised user or practitioner who becomes aware of any adverse event caused or suspected of being caused by a medical device or IVD during the process of using or conducting post-marketing surveillance shall report such events either to the applicant, holder of the certificate of registration, the manufacturer, the authorised representative or the Council.

INVESTIGATIONS

25. The Council may conduct an investigation with regard to a medical device, its manufacturer, importer, exporter or wholesaler if-

a. such a medical device or IVD is recalled in South Africa or any other country;

b. an adverse event is reported in South Africa or any other country;

c. the medical device or IVD is suspected or found not to comply with the requirements of the Act;

d. there is an international alert with regard to such a medical device, IVD or the manufacturer of a medical device or IVD; or

e. for any other reason, the Council deems it fit to conduct an investigation on the medical device or IVD.

OFFENCES AND PENALTIES

26. Any person who fails to comply with, contravenes the provisions of or wilfully furnishes incorrect information in respect of –

a. Regulation 5(1)(c) or (d) with regard to the parallel importation of medical devices or IVDs;

e. Regulations 6 or 7 with regard to the importation or transmission of medical devices or IVDs;

h. Regulation 19 with regard to the information to be furnished annually to the Registrar by the holder of a permit to import or export Schedules 6 & 7 substances;

i. Regulation 8 with regard to the licence to manufacture, act as a wholesaler or distributor of medical devices or IVDs;

j. Regulation 16 with regard to the destruction of medical devices or IVDs;

k. Regulation 17 with regard to the particulars which must appear on a prescription or order for medical devices or IVDs;

l. Regulation 22 with regard to the conduct of clinical trials;

m. Regulation 29 with regard to the advertising of medical devices or IVDs; or

n. Regulation 30 with regard to the labelling of medical devices or IVDs;

o. Regulation 31 with regard to the instructions for use for a medical device

p. Regulation 32 with regard to the instructions for use for an IVD; or

q. sells a medical device or IVD that has expired,

r. Regulation 27 with regard to the compliance to the Essential Principles as confirmed in the Declaration of Conformity,

s. Regulation 24 with regard to reporting of Adverse Events,

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 REGULATIONS

27. (1) Every medical device or IVD shall comply with the standards and specifications which were furnished to the Council on the form prescribed by regulation 11 which have been accepted by the Council with regard to the registration of such medical device or IVD.

(2) Any proposed deviation from accepted standards and specifications as intended in sub-regulation (1) shall be submitted to the Council for prior approval and such deviation shall not be introduced before the said approval has been granted.

BATCH RELEASE FOR PRIORITY IVDs

28. (1) The Council may, with regard to the registration of priority IVDs, require, in terms of section 15 (7) of the Act, that samples of the initial and/or every batch, together with copies of the protocols of testing and copies of the certificate of release issued by the competent authority in the country in which the product was manufactured, be submitted to the Council as an approval or batch release condition.

ADVERTISING OF MEDICAL DEVICES OR IVDs

29. (1) The under mentioned requirements shall apply to any advertisement of a medical device or IVD.

(2) a Medical devices or IVDs which do not contain a scheduled substance and medical devices or IVDs which contain a substance appearing in Schedule 0 or Schedule 1 may be advertised to the public; and

b Medical devices or IVDs which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 may be advertised only for the information of medical practitioners, dentists, veterinarians, pharmacists and other persons authorised to prescribe or in a publication which is normally or only made available to persons referred to therein;

(3) No advertisement for a medical device or IVD may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medical device or IVD with regard to its safety, quality, or performance where such evidence has been accepted by the Council in respect of such medical device or IVD and incorporated into the approved instructions for use of a medical device or IVD.

(4) A written advertisement for a medical device or IVD shall contain-

a. the name of such medical device or IVD;
b. the approved name and quantity of each active ingredient of such medical device or IVD where applicable in lettering having minimum legibility;
c. in the case –
    i of a registered medical device or IVD, the registration number allocated to it in terms of section 15 (6);
    ii of a medical device or IVD 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 Registrar, followed by the words 'Act 101/1965';

(5) In the case of an advertisement for a medical device 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 Council for inclusion in the approved instructions for use of such medical device or IVD.

(6) When a medical device or IVD is advertised verbally for the first time to persons referred to in subregulation 2(b), written information, which shall include at least the information referred to in regulation 31 or regulation 32 as the case may be, shall simultaneously be given to the person to whom the oral advertisement is directed, and when the medical device or IVD is advertised orally on subsequent occasions such information shall be available on request.

LABELLING OF MEDICAL DEVICES OR IVDs

30. (1) The label of each medical device or IVD should contain the following particulars in at least English which must appear on the medical device or IVD itself, or on the packaging of each unit, or on the packaging of multiple devices or IVDs;

(a) name or trade name of the medical device or IVD;

(b) approved intended purpose where practical for use of the medical device or IVD;

(c) product catalogue code where applicable;

(d) name and business address of the manufacturer;

(e) name and business address of the applicant;

(f) where appropriate, an indication that the device contains or incorporates a Scheduled or biological substance;

(g) the lot number where applicable;

(h) the serial number where applicable;

(i) for accessories the serial number may be substituted with a control number and for software it may be substituted with a version number;

(j) the expiry date where applicable;

(k) where there is no indication of the expiry date, the manufacturing date;

(l) an indication of any special storage and/or handling conditions applicable

(m) if the device is supplied sterile, an indication of its sterile state and, where appropriate, the sterilization method;

(n) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package;

(o) warnings or precautions where applicable;

(p) the performance intended where applicable;

(q) where appropriate an indication that the device is intended for:

(i) single use;

(ii) clinical investigation or premarket performance evaluation;

(iii) non-clinical research, teaching or testing purposes;

(iv) presentation or demonstration purposes; and/or

(v) *in vitro* diagnostic use.

(2) If the medical device is a reprocessed medical device the label must state the name of the re-processor and identify the medical device as a reprocessed medical device.

(3) If the IVD kit includes individual reagents and articles that may be made available as separate IVD medical devices, they must comply with the content in sub-regulation (1) of this regulation.

INSTRUCTIONS FOR USE OF MEDICAL DEVICES

31. (1) Each package of a medical device shall have an instruction for use of the medical device that must contain the following information with regard to the medical device in at least English:

(a) name or trade name of the medical device;

(b) name and business address of the manufacturer;

(c) where practical, the approved intended purpose for use of the medical device or IVD including in the case of a medical device, the intended user;

(d) where the manufacturer has included clinical investigations as part of premarket conformity assessment to demonstrate conformity to the safety and performance criteria, a summary of the investigation, outcome data and clinical safety information, or a reference as to where such information may be accessed;

(e) any residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard;

(f) specifications that the user requires to use the device appropriately (e.g. if the device has a measuring function, the degree of accuracy claimed for it);

(g) if the device contains, or incorporates, a medicinal substance and/or material of biological origin, identification of that substance or material, as appropriate;

(h) details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilization, final assembly, calibration, etc.);

(i) any requirements for special facilities, or special training, or particular qualifications of the device user and/or third parties;

(j) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

(i) details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;

(ii) identification of any consumable components and how to replace them;

(iii) information on any necessary calibration to ensure that the device operates properly and safely during its intended life span; and

(iv) methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing medical devices;

(k) an indication of any special transport, storage and/or handling condition that applies;

(l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged before use;

(m) if the device is supplied non-sterile with the intention that it is sterilized before use, the appropriate instructions for sterilization;

(n) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization including information to identify when the device should no longer be reused (e.g. signs of material degradation or the maximum number of allowable reuses);

(o) for devices intended for use together with other medical devices and/or general purpose equipment:

(i) information to identify such devices or equipment, in order to obtain a safe combination; and/or

(ii) information on any known restrictions to combinations of medical devices and equipment;

(p) if the device emits hazardous, or potentially hazardous levels of radiation for medical purposes:

(i) detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; and

(ii) the means of protecting the patient, user, or third party from unintended radiation during use of the device;

(q) information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device which information should cover, where appropriate:

(i) warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;

(ii) warnings, precautions and/or measures to be taken in regard to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;

(iii) warnings, precautions and/or measures to be taken in regard to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);

(iv) if the device administers medicinal or biological products, any limitations or incompatibility in the choice of substances to be delivered;

(v) warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and

(vi) precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction of the patient or user.

(r) warnings or precautions to be taken related to the disposal of the device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:

(i) infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);

(ii) environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation); and

(iii) physical hazards (e.g. from sharps);

(s) for devices intended for use for self-testing, the circumstances when the user should consult with a healthcare professional;

(t) date of issue or latest revision of the instructions for use and, where appropriate, an identification number; and

(u) appropriate maintenance instructions for technical IVD machines, where applicable.

INSTRUCTIONS FOR USE OF IVDs

32. (1) Each package of an IVD shall have an instruction for use of the IVD that must contain the following information with regard to the IVD in at least English:

(a) the name or trade name;

(b) name and address of the manufacturer;

(c) the intended purpose/use, including but not limited to:

(i) what is detected;

(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);

(iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;

(iv) whether it is automated or not;

(v) whether it is qualitative or quantitative;

(vi) the type of specimen(s) required (e.g. serum, plasma, whole blood, tissue biopsy, urine); and

(vii) testing population;

(d) an indication that it is for in vitro diagnostic use;

(e) an indication whether the device is intended for self-testing or near-patient testing;

(f) test principle;

(g) a description of the reagent, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);

Note: IVD kits include individual reagents and articles that may be made available as separate IVDs. In this situation, where appropriate, these IVDs should comply with the instructions for use content in this section.

(h) a list of materials provided and a list of special materials required but not provided;

(i) for IVDs intended for use together with other IVDs or medical devices, and/or general purpose equipment:

  (i) information to identify such devices or equipment, in order to obtain a safe combination; and/or

  (ii) information on any known restrictions to combinations of medical devices and equipment;

(j) an indication of any special storage (e.g. temperature, light, humidity, etc.), storage and/or handling conditions that apply;

(k) in use stability which may include, the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;

(l) if the IVD is supplied as sterile, instructions in the event of the sterile packaging being damaged before use;

(m) information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the IVD which information should cover, where appropriate:

  (i) warnings, precautions and/or measures to be taken in the event of malfunction of the IVD or its degradation as suggested by changes in its appearance that may affect performance;

  (ii) warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;

  (iii) warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);

  (iv) precautions related to materials incorporated into the IVD that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction;

(n) any warnings and/or precautions related to potentially infectious material that is included in the IVD;

(o) where relevant, requirements for special facilities (e.g. clean room environment) or special training (e.g. radiation safety), or particular qualifications of the device user;

(p) conditions for collection, handling, and preparation of the specimen;

(q) details of any preparatory treatment or handling of the IVD before it is ready for use (e.g. reconstitution, calibration, etc.);

(r) the information needed to verify whether the IVD is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

(i) details of the nature, and frequency, of preventative and regular maintenance (including cleaning and disinfection);

(ii) identification of any consumable components and how to replace them;

(iii) information on any necessary calibration to ensure that the IVD operates properly and safely during its intended life span;

(iv) methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing IVD (e.g. contaminated surfaces);

(s) where relevant, recommendations for quality control procedures;

(t) the metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order;

(u) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing should be considered;

(v) analytical performance characteristics, such as sensitivity, specificity, and accuracy (which is a combination of trueness and precision);

(w) where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity;

(x) where relevant, reference intervals;

(y) information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen/sample) that may affect the performance of the assay;

(z) warnings or precautions to be taken related to the disposal of the device, its accessories, and the consumables used with it, if any, which information should cover, where appropriate:

(i) infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin);

(ii) environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation); and

(iii) physical hazards (e.g. explosion);

(aa) for IVDs intended for use by lay persons, the circumstances when the user should consult with a healthcare professional;

(bb) where relevant, a bibliography;

(cc) date of issue or latest revision of the instructions for use and, where appropriate, an identification number.

(dd) appropriate maintenance instructions for technical IVD machines, where applicable

CUSTOM MADE MEDICAL DEVICES

33. (1) All custom made medical devices must be manufactured and sold complying with the guidelines applicable to medical devices.

RECORD OF IMPLANTABLE MEDICAL DEVICES AND CUSTOM MADE MEDICAL DEVICES

34. (1) A permanent record in respect of all Class D, implantable or high-risk custom made medical devices shall be kept on all premises where such devices are dispensed or sold and shall contain the following information:

a. the name of the medical device;
b. the date on which the prescription or order for the implantable or custom made medical device was dispensed or sold;
c. the model number, batch number, and serial number (if applicable);
d. the name, address and identity number of the patient;
e. where applicable the name of the medical practitioner, dentist, veterinarian or any other authorised person who issued the prescription or order and who will, in the case of an implantable medical device, be responsible for the insertion of the medical device;
f. the name and address of the health establishment;

g. the name of the manufacturer of the implantable or custom made medical device; and

h. information relating to the design, manufacturing and performance of the medical device including expected performance.

(2) A prescription or order record shall be retained at the business address of the seller for a period of at least five years beyond the expected life of the medical device.

(3) The manufacturer or wholesaler of Class D or implantable or custom made medical devices shall keep a record of Class D or implantable or custom made medical devices in the form of invoices that will reflect:

a. the date and transaction of every sale;

b. the proprietary name of the medical device;

c. the name and address of every purchaser;

d. the quantities sold; and

e. the batch number.

(4) A record referred to in subregulation (3) shall be kept for a period of five years from the date of sale.

TRANSITIONAL ARRANGEMENTS - UNLICENCED MANUFACTURERS, IMPORTERS, EXPORTERS AND WHOLESALERS

35. (1) Manufacturers, importers, exporters or wholesalers selling medical devices or IVDs in the Republic at the time of the commencement of these regulations shall, subject to regulation 8, be deemed to be trading legally.

(2) The Council shall issue notices in the Gazette calling for the licensing of manufacturers, importers, exporters and wholesalers which notices will stipulate the conditions and time periods for licensing.

TRANSITIONAL ARRANGEMENTS - UNREGISTERED MEDICAL DEVICES AND IVDs

36. (1) Unregistered medical devices or IVDs sold in the Republic at the time of the commencement of these regulations shall, subject to regulations 11, be deemed

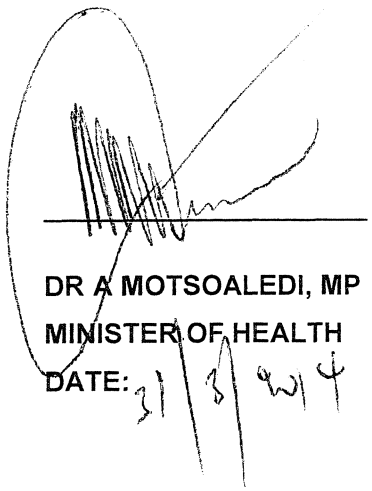
to be sold legally until such time as the call-up notice period for the medical device or IVDs has expired.

(2) The Council shall issue notices from time to time in the Gazette calling for the registration of medical devices and IVDs which notices will stipulate which classes of medical devices and IVDs must be registered and providing the conditions and time periods for the application for registration.

(3) Notwithstanding sub-regulation 1 the Council may require any medical device or IVD to comply with any requirements that the Council may determine in order to ensure that the medical device or IVD is safe, of performance and of good quality.

COMMENCEMENT

37. These Regulations are called Regulations relating to Medical Devices and *In vitro* Diagnostic Medical Devices (IVDs) made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) and will commence upon the date signed by the minister.



DR A MOTSOALEDI, MP
MINISTER OF HEALTH
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