DEPARTMENT OF HEALTH

NO. 1515 **09 DECEMBER 2016**

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

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

I, Dr A Motsoaledi, the Minister of Health has, in consultation with the Medicines Control Council, in terms of section 35(1)(xxvii) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), made the regulations in the Schedule.

SCHEDULE

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1. DEFINITIONS

In these Regulations a word or expression defined in the Act bears the meaning so assigned and unless the context otherwise indicates-

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

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

"authorised representative" means a natural person, resident in the Republic of South Africa, who-

(a) has the written mandate to represent a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic;

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(b) acts on behalf of a manufacturer, importer, distributor, wholesaler, retailer or service provider for specified tasks with regard to the latter's obligations and in whose name the manufacturer licence, distributor licence, wholesaler licence or certificate of registration is issued; and

(c) is responsible for all aspects of the medical device or IVD, including performance, quality, safety and compliance with conditions of registration, clinical trials or clinical investigations;

"batch number", "lot number" or "serial number" or "control number" or "version number" means a unique number or combination of numbers or cyphers allocated to a lot or a batch or a unique medical device or unique accessory to a medical device in the case of "control number", or unique software in the case of "version number" by the manufacturer;

"biological substance" means a substance derived from a human, animal or a micro-organism;**"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);

"clinical investigation or clinical trial" 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, through assessment and analysis of the clinical data pertaining to a medical device, to discover or verify the safety or clinical performance of the medical device or IVD when used as intended by the manufacturer;

"clinical performance study of an IVD" means a study undertaken to establish or confirm the clinical performance of an 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, to determine that a medical device or IVD is safe and performs as intended and that the medical device or IVD fulfils the Essential Principles of Safety and Performance for Medical Devices or IVDs, as determined by the Council;

"conformity assessment body" means a body corporate or other legal entity, locally or internationally, accredited by SANAS or an international body recognised by the Council as competent to carry out the assessment, verification, inspection testing or certification, as applicable, of medical devices or IVDs, before they are placed on the market by manufacturers, according to criteria determined by the Council;

"**conformity assessment certificate**" means a certificate issued, by a Conformity Assessment Body, to demonstrate compliance with the Essential Principles of Safety and Performance for Medical Device and IVD requirements;

"custom made medical device" means a medical device-

(a) specifically made in accordance with a written prescription or order given by a person authorised for the same by virtue of professional qualifications;

(b) specifically made in accordance with specific design characteristics;

(c) which is intended for the sole use of a particular user; and

(d) which excludes mass produced medical devices that only need adaptation to meet the specific requirements of the health professional user;

"declaration of conformity" means the procedures 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 the Council, which are subject to audit and surveillance, are fulfilled;

"distributor" means a natural or legal person who-

(a) imports or exports a medical device or IVD, which is on the register for medical devices or on the register for IVDs in its final form, wrapping and packaging, with a view to the medical device or IVD being placed on the market under the natural or legal person's own name; and
(b) sells the medical device or IVD to a healthcare professional, healthcare institution, wholesaler or the user;

"essential principles" means the requirements relating to the safety and performance characteristics of medical devices and IVDs determined by the Council;

"expiry date" means the date up to which a medical device or IVD retains 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 may not be sold to the public or used;

"family" means a medical device or IVD comprising of the same type of medical 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, procedure tray, 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" 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 performance, quality, safety and compliance with conditions of registration;

"implantable device" means a medical device, including a medical device that is partially or wholly absorbed, which -

(a) 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; and

(b) is intended to remain in place for at least 30 days after the procedure;

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

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

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

"manufacture" means operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, reprocessing, releasing, packaging, repackaging, labelling, and refurbishing of a medical device or IVD, as the case may be, and includes 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) a 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 or her behalf by a third party; or

(b) any other person who assembles, packages, reprocesses, 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, except a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients;

"misbranded" means a medical device labelling is false, misleading, inaccurate or fails to provide information as required;

"modification" in relation to a medical device or IVD means–

(a) any significant change in a medical device or IVD;

(b) any change in the purpose of a medical device or IVD, where significant change may include–

(i) the manufacturing process;

(ii) facility or equipment;

(iii) the quality control measures used to control the quality and sterility of a medical device or IVD; or

(iv) a change of the materials used in manufacture, the design of a 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 a medical device or IVD;

(c) any new or extended use, any addition or deletion of a contra-indication of a medical device or IVD; and

(d) any change to the period used to establish its expiry date;

"near patient testing" or **"point of care 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, a patient;

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

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

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

"refurbish" in relation to a medical device or IVD means the whole or part of a medical device or IVD is substantially rebuilt, re-equipped, reworked 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 or IVD that is used for the purpose originally intended by the original manufacturer of the original medical device or IVD, and without prejudice to the generality of the foregoing, refurbishment of a medical device may involve any or all of the following actions including, but not limited to, repair, rework, update of software or 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 or intended use as defined in its original registration;

"research use only IVD" ("RUO IVD") means an IVD labelled for "research use only" and "for investigational use only" and may not be used for clinical diagnostic purposes;

"reprocess" means the activity carried out on a used medical device in order to allow its safe re-use including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the used medical device;

"self-testing" means testing performed by a lay person;

"single use" in terms of a medical device means one use of a medical device on an individual or IVD on a sample during a single procedure and then the medical device or IVD is disposed of and is not reprocessed and not used again;

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

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

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

2. Manner and conditions for allowing international tendering

(1) The State may tender for a medical device or IVD internationally if the 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 may not be procured by international tender unless the medical device or IVD is registered.

3. Importation of medical devices and IVDs into the Republic

(1) A person may not import a medical device or IVD into the Republic except through one of the following ports of entry:

(a) Cape Town International Airport or harbour;

(b) Port Elizabeth Airport or harbour;

(c) King Shaka International Airport or Durban harbour; or

(d) OR Tambo International Airport.

(2) Despite sub-regulation 3(1), used medical devices or IVDs may be imported by a manufacturer for purposes of service, repair, refurbishing or maintenance.

(3) A person may only import a medical device or IVD if that person-

(a) is licensed in terms of section 22C(1)(b) 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 the unregistered medical devices or IVDs.

4. Transmission of medical devices or IVDs through the Republic

(1) Medical devices and IVDs that are transmitted through the Republic must-

(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 sub-regulation (1) must comply with the specified storage conditions determined by the Council.

5. Licence to manufacture, import, export or act as a distributor or wholesaler of medical devices or IVDs

(1) A manufacturer, wholesaler or distributor referred to in section 22C(1)(b) of the Act must-

(a) prior to commencing business-

(i) apply to the Council for-

(aa) a manufacturer licence to manufacture, import or export medical devices or IVDs; or

(bb) a distributor licence to import, export and distribute medical devices or IVDs; or

(cc) a wholesale licence to act as wholesaler of medical devices or IVDs;

(ii) appoint and designate an authorised representative who must reside in South Africa-

(aa) be responsible to the Council for compliance with the Act; and

(bb) control the manufacturing, distribution, wholesaling and the sale of medical devices or IVDs.

(b) submit to the Registrar an application for a licence, on a form approved and provided by the Council;

(c) as part of the application, provide acceptable documentary proof of-

(i) the particulars of the owner of the business;

(ii) the particulars of the authorised representative; and

(iii) certification to a Quality Management System for medical devices and IVDs as determined by the Council;

(d) specify, as determined by the Council, the medical devices or IVDs or group or family of medical devices or IVDs to be manufactured, imported, exported or distributed and sold; and

(e) pay the application fee.

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

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

(4) If the Council is satisfied that-

(a) the person referred to in sub-regulation (1) complies with the prescribed requirements;

(b) the application for a licence-

(i) to manufacture, import or export medical devices or IVDs; or

(ii) to act as a distributor; or

(iii) to act as a wholesaler of medical devices or IVDs

complies with the prescribed requirements; and

the authorised representative is able to provide certified evidence of certification to a Quality Management System as determined by Council, the Council must approve, with or without conditions, the application and issue the 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 the register.

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

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

(8) An 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 whom an entry has been removed as contemplated in sub-regulation (8), must be notified of the removal and a certificate issued in respect of the registration in question must be considered to be cancelled as from the date on which notice has been given.

(10) The Council may, subject to sub-regulation (11), direct the Registrar to remove the name of a licensee from the register if -

(a) the licensee does not comply with the Act or the conditions of a licence;

(b) the authorised representative fails to control the manufacturing or distribution, wholesaling or sale of the medical devices or IVDs; or

(c) the licensee fails to furnish written reasons within the period stated in the notice referred to in sub-regulation (11).

(11) Before directing the Registrar to remove the name of a licensee from the register, the Council must-

(a) give notice to the licensee of its intention to remove the name of the licensee from the register and to close the licensee's business; and

(b) invite the licensee to furnish written reasons, within 21 days of the notice, why the licensee's licence must not be removed from the register and the business closed.

6. Period of validity of licence and renewal of licence

(1) A licence issued in terms of regulation 5 is valid for a period of five (5) years from the date of issue.

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

(3) An application for the renewal of a licence must -

(a) contain at least the information or documentation referred to in regulation 5(1)(c), as the case may be;

(b) be accompanied by the prescribed fee; and

(c) be made at least 90 days before the expiry of the existing licence.

7. Appeal against decision of Council

(1) A person aggrieved by a decision of the Council may, as contemplated in section 24 of the Act, lodge an appeal against the decision, in writing, within 30 days of being notified of the decision of the Council.

(2) Notice of the appeal must be submitted to the Chairperson of the Council, for attention the Registrar, Medicines Control Council, Private Bag X828, Pretoria, 0001

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

(4) The Registrar must, within 30 days of receipt of a notice of appeal, in the absence of legal representatives, meet with the appellant to try and resolve the matter.

(5) If the matter is not resolved as contemplated in sub-regulation (4), the appellant may, within 30 days of being notified by the Registrar of the failure to resolve the matter, and upon payment of the prescribed fee, request the Minister to convene an appeal committee.

(6) The appeal committee -

(a) must determine the procedure for its hearings;

(b) may, if it considers it 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 his or her control a 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 a document;

(c) must, if it calls for oral evidence or argument-

(i) determine the date, time and place for the appeal and must communicate these in writing to the appellant and the Council; and

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

(7) A person appearing before the appeal committee may be represented by a legal practitioner.

(8) The appeal committee must consider the appeal and make a decision within a period of 30 days from the date on which it first meets to hear the appeal.

8. Application for registration of a medical device or IVD

(1) A person residing and doing business in the Republic may apply for the registration of a medical device or IVD.

(2) An application for the registration of a medical device or IVD must include the particulars of the authorised representative in South Africa who is responsible for communication with the Council.

(3) An application for the registration of a medical device or IVD must be made on the appropriate form obtainable from the Registrar and must be accompanied by -

(a) the completed application form;

(b) a proposed label for use on the medical device or IVD, if applicable;

(c) the instructions for use of the medical device or IVD;

(d) where applicable,

(i) a copy of the manufacturer licence or distributor licence together with a conformity assessment certificate of a Quality Management System for the local medical device establishment, as determined by the Council; and

(ii) a certified copy of the conformity assessment certificate to a quality standard, as determined by the Council, for the medical device or IVD to be registered, and which is issued by a Conformity Assessment Body;

(e) any other information as the Council may determine; and

(f) the application fee.

(4) The information referred to in sub-regulation (3) must, at least, be in English.

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

(a) Particulars of the prospective holder of the certificate of registration:

(i) Name;

(ii) Business Address;

(iii) Postal Address;

(iv) Telephone Number;

(v) Fax Number, where available;

(vi) e-mail address; and

(vii) contact details of the authorised representative referred to in sub-regulation (2).

(b) Particulars of the medical device or IVD:

(i) The name and group or family name, make and model, where applicable;

(ii) intended purpose or use;

(iii) classification and registration status in recognised authorities outside the Republic, as determined by the Council, and proposed classification in the Republic;

(iv) nomenclature system code;

(v) in the case of a combination device, the name and quantity of the scheduled substances or biological substances;

(vi) the name and physical address of the original manufacturer; and

(vii) the name and physical address of the clinical investigation sites, 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 for registration of a medical device or IVD must be accompanied by a declaration of conformity by the authorised representative as determined by the Council.

(8) An application must be made in respect of each individual medical device or IVD, or medical device or IVD group or family or modification thereof, as determined by the Council.

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

(a) A certified copy of the certificate of registration or premarket approval, where applicable;

(b) instructions for use, where applicable;

(c) conditions of registration; and

(d) any other information determined by the Council.

9. Information that must appear in register for medical devices or IVDs

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

(a) The name and group or family and the 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 device, the name and quantity of the scheduled substances or biological substances in the medical device;

(d) the intended purpose or use of the medical device or IVD;

(e) the name of the holder of the certificate of registration;

(f) the name and address of the original manufacturer;

(g) the date of registration of the medical device or IVD;

(h) the conditions of registration of the medical device or IVD;

(i) the class of medical device or IVD; and

(j) the nomenclature system code allocated to the medical device or IVD.

10. Amendment to medical device and IVD Register

(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 in the medical devices or IVDs register with regard to a particular medical device or IVD.

(2) The application referred to in sub-regulation (1) must be accompanied by the 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 holder of a certificate of registration and the authorised representative;

(c) a declaration by the authorised representative that the information furnished is complete and accurate;

(d) the details of the amendment applied for;

(e) the manufacturer licence number of the manufacturer or the distributor licence number of the distributor; and

(f) any other information determined by the Council.

11. Classification of medical devices and IVDs

(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, user or to public health.

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

(3) The Council must determine the classification of medical devices and IVDs in accordance with the classification rules.

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

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

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12. Registration Certificate

The Registrar must, after a medical device or IVD has been registered, issue a registration certificate substantially in the form shown below:

MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT NO. 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 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 name and quantity of the scheduled substance(s), or biological substance(s)
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 physical address of the original manufacturer .....
9. Date of registration .....

Registrar

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

13. Parts and components

(1) A person who sells an article intended specifically to replace an identical or similar integral part or component of a medical device or IVD, that is defective or worn, in order to maintain or re-establish the function of the medical device or IVD without significantly changing its performance or safety characteristics, must–

(a) ensure that the article does not adversely affect the safety and performance of the medical device or IVD; and

(b) keep substantiating evidence and on request, make the evidence available to the Council.

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(2) An article that is intended specifically to replace a part or component of a medical device or IVD and that significantly changes the performance or safety characteristics of the medical device or IVD is considered to be a medical device or IVD.

14. Destruction of medical devices or IVDs

(1) A medical device or IVD may not be disposed of into a municipal sewerage system.

(2) The destruction or disposal of a medical device or IVD, must be conducted in a manner determined by the Council.

15. Method of taking samples during investigation, certificate to be issued and reporting of analysis results

(1) An inspector may, take a sample, or any quantity of samples, of a medical device or IVD for purposes of testing, examination or analysis by a person suitably qualified within his or her professional scope of practice, such as a clinical engineer, technician, or pathologist.

(2) The sample or samples contemplated in sub-regulation (1) must -

(a) be taken in the presence of the person who is in charge of the medical device or IVD, or in the absence of that 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

(d) be transmitted by any suitable means to a person suitably qualified within his or her professional scope of practice such as an analyst, clinical engineer, technician 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) The suitably qualified person referred to in sub-regulation (1) must, as soon as possible after receipt of the sample, test, examine or analyse the sample and report the results of the test, examination or analysis.

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

(5) Despite sub-regulation (1), the Council may require a 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 the sample.

(6) A certificate issued in terms of this regulation or a report contemplated in sub-regulation (3), must be submitted to the Registrar within 7 days from the date of issue.

16. Conduct of clinical trial and clinical investigation

(1) A person desiring to initiate or conduct–

(a) a clinical trial or clinical investigation in respect of an unregistered medical device;

(b) a clinical performance assessment for an IVD; or

(c) a new intended purpose of a registered medical device or IVD,

must apply to the Council on a form, determined by the Council, for authorisation to conduct the clinical trial, clinical investigation or clinical performance assessment.

(2) The application referred to in sub-regulation (1) must be accompanied by the prescribed fee and must contain at least the following information:

(a) A clinical investigation plan or clinical trial or clinical performance assessment for an IVD protocol;

(b) an investigator's brochure containing, where applicable, relevant pre-clinical, mechanical, electrical and radiation data and where applicable, human or animal clinical data with the medical device or IVD concerned;

(c) the Curriculum Vitae of the investigator;

(d) a signed declaration by the applicant and the investigator that they are familiar with, and understand the protocol, and will, in the conduct of the clinical investigation or clinical trial, comply with Good Clinical Practice as determined by the Council;

(e) informed consent documents and endorsements by an ethics committee recognised by the Council; and

(f) the name and address of the institution where the clinical trial or clinical investigation will be conducted.

(3) The clinical investigation plan, clinical trial or clinical performance assessment for an IVD protocol referred to in sub-regulation (2)(a) must contain at least the following information:

(a) The number of human or animal subjects, as applicable, to be involved in the clinical investigation, clinical trial or clinical performance assessment for an IVD;

(b) the name of the investigator who must be-

(i) an appropriately qualified and competent person approved by the Council;

(ii) resident in the Republic; and

(ii) in charge of the sites where clinical trials or clinical performance assessment for an IVD are conducted;

(c) the quantity of the investigational medical device or IVD units to be used in the clinical trial, clinical investigation or clinical performance assessment for an IVD;

(d) information in respect of the design, manufacture and expected performance of the medical device or IVD; and

(e) any other information determined by the Council.

(4) A clinical investigation and a clinical trial or a clinical performance assessment for an IVD must be conducted in accordance with the guidelines for good clinical practice determined by the Council.

(5) A person may not conduct a clinical investigation, a clinical trial or a clinical performance assessment for an IVD referred to in sub-regulation (1), without the authorisation of the Council.

(6) The person conducting the clinical investigation, clinical trial or clinical performance assessment for an IVD must submit to the Council-

(a) progress reports after every six months from the date when the clinical investigation, clinical trial or clinical performance assessment for an IVD was started, and 30 days after the completion or termination of the clinical investigation, clinical trial or clinical performance assessment for an IVD; and

(b) adverse event reports immediately or as soon as practically possible.

(7) The Council may-

(a) request additional information;

(b) inspect a clinical investigation, clinical trial or clinical performance assessment for an IVD; or

(c) withdraw the authorisation to conduct a clinical investigation, clinical trial or clinical performance assessment for an IVD, if the Council is of the opinion–

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(i) that the safety of the subjects of the clinical investigation, clinical trial or clinical performance assessment for an IVD is compromised; or

(ii) that the scientific reasons for conducting the clinical investigation, clinical trial or clinical performance assessment for an IVD, have changed.

(8) (a) The following information for a medical device or IVD referred to in sub-regulation (1) must be provided, where applicable:

(i) The intended purpose or use of the investigational medical device in the proposed clinical investigation or clinical trial;

(ii) the populations and indications for which the investigational medical device is intended;

(iii) the name or number of the model or type, including software version and accessories, if any, to permit full identification;

(iv) a description as to how traceability is to be achieved during and after the clinical investigation, (e.g. by assignment of lot numbers, batch numbers or serial numbers);

(b) The medical device or IVD must–

(i) where practical, be labelled with the name and address of the premises where the clinical investigation, clinical trial or clinical performance assessment for an IVD is to be carried out; and

(ii) be labelled "for investigational use only".

(9) The Council may, subject to such conditions as may be determined by the Council, authorise the conduct of a clinical investigation, clinical trial or clinical performance assessment for an IVD.

17. Adverse event reporting and vigilance for medical devices or IVDs

(1) An authorised representative or a holder of a certificate of registration in respect of a medical device or IVD must inform the Council, in the manner and within the time frame determined by the Council, of a suspected adverse event, reported to him or her, occurring as a result of the use of the medical device or IVD.

(2) An authorised representative or a holder of a certificate of registration referred to in sub-regulation (1) must -

(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 event;

(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 to the Council, if required to do so -

(i) case reports of suspected medical device adverse events in respect of the medical device or IVD;

(ii) where applicable, medical device or IVD usage figures, periodic safety update reports and performance studies; and

(iii) any other data requested by the Council.

(d) keep and maintain or have access to records of the adverse event data in respect of his or her or its medical devices or IVDs.

(3) Nothing in this regulation may be interpreted as prohibiting a person from reporting an adverse event to the Council.

(4) Despite sub-regulation (1) or (3), a user who becomes aware of an adverse event caused or suspected of being caused by a medical device or IVD during the process of using or conducting post-marketing surveillance, must report the event either to the licensee, holder of the certificate of registration, the manufacturer, the authorised representative or the Council.

18. Investigation

(1) The Council may conduct an investigation with regard to a medical device or IVD, its manufacturer, distributor or wholesaler if-

(a) the medical device or IVD is recalled in South Africa or any other country;

(b) a medical device or IVD 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 the medical device, IVD or the manufacturer of the medical device or IVD; or

(e) for any other reason, the Council considers it necessary to conduct an investigation on the medical device or IVD.

19. Offences and penalties

(1) A person who fails to comply with, contravenes the provisions of, or wilfully furnishes incorrect information in respect of –

(a) regulations 3 or 4 with regard to the importation or transmission of medical devices or IVDs;

(b) regulation 5 with regard to the licence to manufacture, act as a distributor or act as a wholesaler of medical devices or IVDs;

(c) regulation 14 with regard to the destruction of medical devices or IVDs;

(d) regulation 16 with regard to the conduct of clinical trials;

(e) regulation 21 with regard to the advertising of medical devices or IVDs;

(f) regulation 22 with regard to the labelling of medical devices or IVDs;

(g) regulation 23 with regard to the instructions for the use of a medical device;

(h) regulation 24 with regard to the instructions for use of an IVD;

(i) regulation 20 with regard to the compliance to the Essential Principles confirmed in the declaration of conformity; or

(j) regulation 17 with regard to reporting of adverse events and vigilance,

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

(2) A person who sells a medical device or IVD that has expired is guilty of an offence and upon conviction is liable to a fine, or to imprisonment for a period not exceeding 10 years.

20. Compliance with requirements

(1) A medical device or IVD must conform to the standards and specifications which were furnished to the Council on the form referred to in regulation 8 and which form has been accepted by Council in respect of the medical device or IVD.

(2) A medical device or IVD must conform to the Essential Principles furnished to the Council with a declaration of conformity referred to in regulation 8(7).

(3) A proposed deviation from accepted standards and specifications referred to in sub-regulations (1) and (2), must be submitted to the Council for prior approval.

21. Advertising of medical devices or IVDs

(1) The following requirements apply to an advertisement of a medical device or IVD:

(a) Only Class A and Class B medical devices and IVDs may be advertised to the public or a lay person.

(b) despite sub-regulation (a), male or female condoms may be advertised to the public.

(c) an advertisement for a medical device or IVD may not contain a statement which deviates from, is in conflict with or goes beyond, the evidence submitted in the application for registration of the medical device or IVD with regard to its safety, quality, or performance where the evidence has been–

(i) accepted by the Council in respect of the medical device or IVD; and

(ii) incorporated into the approved instructions for use of the medical device or IVD.

(d) a written advertisement for a medical device or IVD must contain-

(i) the name of the medical device or IVD; and

(ii) in the case of a registered medical device or IVD, the registration number allocated to the medical device or IVD;

(e) (i) when a Class C or Class D medical device or IVD is advertised for the first time to a prospective user, written information, which must include at least the information referred to in regulation 23 or regulation 24 as the case may be, must simultaneously be given to the person to whom the oral, electronic or printed advertisement is directed; and

(ii) when the medical device or IVD is advertised on subsequent occasions, the information must be available on request.

22. Labelling of medical device or IVD

(1) The label of each medical device or IVD must contain the following particulars:

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

(b) product description and intended use;

(c) a product catalogue code, where applicable;

(d) the name and business address of the manufacturer;

(e) the name and business address of the holder of the certificate of registration;

(f) where appropriate, an indication that the medical 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 the special storage or handling conditions applicable;

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

(p) where appropriate an indication that the medical device is intended for-

(i) single use;

(ii) clinical investigation or premarket clinical performance study;

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

(iv) presentation or demonstration purposes;

(v) *in vitro* diagnostic use or Laboratory Developed Tests; and

(vi) where relevant, "for professional use only" or "near patient testing" or "point of care" or "self-testing".

(2) The label of each medical device or IVD must be in at least English and must appear–

(a) on the medical device or IVD itself; or

(b) on the packaging of each unit; and

(c) on the packaging of multiple medical devices or IVDs.

(3) 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.

(4) If an IVD kit includes individual reagents and articles that may be made available as separate IVD medical devices, they must comply with the requirements set out in sub-regulation (1).

23. Instructions for use of medical device

(1) The instructions for use must contain the following information in at least English:

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

(b) the name and business address of the manufacturer;

(c) where practical, the approved intended purpose or use of the medical device and where appropriate, the intended user;

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

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

(f) if the medical device contains, or incorporates, a scheduled substance or a biological substance, identification of that substance, as appropriate;

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

(h) any requirements for special facilities, or special training, or particular qualifications of the medical device user or third parties;

(i) the information needed to verify whether the medical 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 medical 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;

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

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

(l) if the medical device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;

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

(n) for medical devices intended for use together with other medical devices or general purpose equipment-

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

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

(o) if the medical 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 medical device;

(p) information that allows the user and patient to be informed of warnings, precautions, measures to be taken and limitations of use regarding the medical device which information must cover, where appropriate-

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

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

(iv) if the medical device administers a scheduled substance or a biological substance, any limitations or incompatibility in the choice of substance to be delivered;

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

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

(q) warnings and precautions to be taken related to the disposal of the medical device, its accessories and the consumables used with it, if any. This information must 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);

(r) for medical devices intended for use by a lay-person, the circumstances when the user must consult with a healthcare professional;

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

(t) appropriate service and maintenance instructions for technical equipment and medical devices, where applicable.

(2) Instructions for the use of a medical device must be included with the sale of each medical device, however, instructions for the use of Class A medical devices must be included, where applicable.

24. Instruction for use of IVD

(1) The instructions for use must contain the following in at least English:

(a) The name or trade name;

(b) the name and address of the manufacturer;

(c) the intended purpose and use, including but not limited to-

(i) what is detected;

(ii) its function;

(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 specimens 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 and, where relevant, for "professional use only", for "near patient testing", for "point of care", for "self-testing" or for "research use only";

(e) the intended user, as appropriate;

(f) the 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) the composition of the reagent product by nature and concentration of the active ingredients of the reagents or kit as well as a statement, where appropriate, that the medical device contains other ingredients which might influence the measurement;

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

j) for IVDs intended for use together with other IVDs or medical devices, or general purpose equipment–

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

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

(k) an indication of any special storage and handling conditions that apply;

(l) 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;

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

(n) information that allows the user to be informed of warnings, precautions, measures to be taken and limitations of use regarding the IVD, which information must cover, where appropriate-

(i) warnings, precautions and 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 measures to be taken with 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 measures to be taken with regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment including electromagnetic interference emitted by the medical device affecting other equipment, where applicable; and

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

(o) warnings and precautions related to potentially infectious material that is included in the IVD;

(p) where relevant, requirements for special facilities including clean room environment, radiation safety or particular qualifications of the medical device user;

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

(r) details of any preparatory treatment or handling of the IVD before it is ready for use including reconstitution and calibration where applicable;

(s) 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; and

(iv) methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing an IVD;

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

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

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

(w) analytical performance characteristics, such as sensitivity, specificity, and accuracy;

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

(y) where relevant, reference intervals;

(z) information on interfering substances or limitations such as visual evidence of hyperlipidaemia or haemolysis, age of specimen that may affect the performance of the assay;

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

(i) infection or microbial hazards;

(ii) environmental hazards; and

(iii) physical hazards;

(bb) for an IVD intended for use by a lay person, the circumstances when the user must consult with a healthcare professional;

(cc) where relevant, a bibliography;

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

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

(2) Instructions for the use of an IVD must be included with the sale of each IVD, however, instructions for use for Class A IVDs must be included, where applicable.

25. Custom made medical device

A custom made medical device must be manufactured and sold in compliance with the guidelines applicable to medical devices.

26. Record of implantable medical device and custom made medical device

(1) A permanent record in respect of a Class D implantable medical device and a high-risk custom made medical device must be kept on the premises by the healthcare institution or healthcare professional where the medical devices are sold to the patient, and must contain the following information:

(a) The name and the product code of the medical device;

(b) the date on which the order for the implantable or custom made medical device was raised;

(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 user and, in the case of an implantable medical device, the person responsible for the implantation 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) The order record must 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, distributor or wholesaler of Class D or implantable custom made medical devices must keep a record of Class D or implantable custom made medical devices in the form of invoices that must reflect-

(a) the date of 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 or serial number.

(4) A record referred to in sub-regulation (3) must be kept for a period of fifty years from the date of sale.

27. Transitional arrangements regarding unlicensed manufacturer, distributor and wholesaler

(1) A manufacturer, distributor or wholesaler who, at the time of the commencement of these Regulations, sells medical devices or IVDs in the Republic is, subject to regulation 5, considered to be trading legally.

(2) The Council must issue a notice in the *Gazette* calling for the licensing of unlicensed manufacturers, distributors and wholesalers, which notice must stipulate the conditions and time periods for licensing and that, during the process of licensing, the unlicensed manufacturers, distributors and wholesalers are considered to be trading legally.

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28. Transitional arrangements regarding unregistered medical devices and IVDs

(1) An unregistered medical device or IVD sold in the Republic at the time of the commencement of these Regulations is, subject to regulation 8, considered to be sold legally until such time as the call-up notice period referred to in sub-regulation (2),for the medical device or IVD, has expired.

(2) The Council must, from time to time, issue a notice in the *Gazette* calling for the registration of medical devices and IVDs which notice must-

(a) stipulate which classes of medical devices and IVDs must be registered; and

(b) provide for the conditions and time periods for the application for registration.

(3) Despite sub-regulation (1), the Council may require a medical device or IVD to comply with the requirements that the Council may determine in order to ensure that the medical device or IVD meets the Essential Principles of safety and performance, determined by the Council.

29. Short title

These Regulations are called Regulations relating to Medical Devices and *In Vitro* Diagnostic Medical Devices (IVDs).

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 14/11/2016