

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**LIST OF CONTENTS**

1. Definitions
2. Manner and conditions for allowing international tendering
3. Importation of medical devices and IVDs into the Republic
4. Transmission of medical devices or IVDs through the Republic
5. Licence to manufacture, import, export, or act as a distributor or wholesaler of medical devices or IVDs
6. Period of validity of licence issued in terms of regulation 5 and renewal of licences
7. Appeal against the decision of the Council
8. Application for registration of a medical device or IVD
9. Information that must appear in the register for medical devices or IVDs
10. Amendment to the medical devices and IVDs register
11. Classifications of medical devices and IVDs
12. Registration certificate
13. Parts and components
14. Destruction of medical device and IVD

15. Method of taking samples during investigation, certificate to be issued and reporting of analysis results
16. Conduct of clinical trials and clinical investigations
17. Adverse event reporting & vigilance
18. Investigation
19. Offences and penalties
20. Compliance with requirements
21. Advertising of medical device or IVD
22. Labelling of medical device or IVD
23. Instructions for Use of medical device
24. Instructions for Use of IVD
25. Custom made medical devices
26. Record of implantable medical devices and custom made medical devices
27. Transitional arrangements - unlicensed manufacturer, distributor and wholesaler
28. Transitional arrangements - unregistered medical devices and IVDs
29. Short title

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;

- (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 IVDscomplies with the prescribed requirements; andthe 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.

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.

- (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
 - (iii) 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-

- (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

- (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

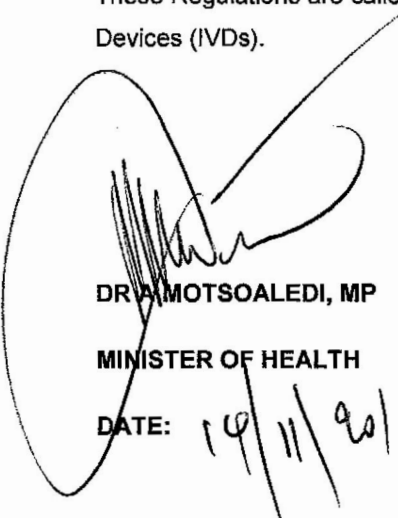
- (1) A manufacturer, distributor or wholesaler who, at the time of the commencement of these Regulations, sells medical devices or IVDs in the Republic is, subject to regulation 5, considered to be trading legally.
- (2) The Council must issue a notice in the *Gazette* calling for the licensing of unlicensed 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.

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

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (MOLAO 101 WA 1965)**MELAWANA YE MALEBANA LE DIDIRIŠWA TŠA BONGAKA LE DIDIRIŠWA TŠA PHEKOLO KA IN VITRO (di-IVD) TŠA BONGAKA**

Nna, Dr A Motsoaledi, Tona ya Maphelo, ka therišano le Khansele ya Taolo ya Dihlare, go ya ka karolo 35(1)(xxvii) ya *Medicines and Related Substances Act, 1965* (Molao 101 wa 1965), ke dirile melawana Šetuleng.

ŠETULE**LENANEO LA DIKAGARE**

1. Dihlalošo
2. Mokgwa le dipeelano bakeng sa tumello ya dithentara tša boditšhabatšhaba
3. Didirišwa tša bongaka le di-IVD tša ditšwantle mo Rephabliki
4. Thomelo ya didirišwa tša bongaka goba di- IVD mo Rephabliki
5. Laesense ya tšweletšo, ditšwantle, diromelwantle, goba go dira bjalo ka mophatlalatši goba rakgwebokgolo ya didirišwa tša bongaka goba di- IVD
6. Nako ya go šoma ga laesense yeo e neilwego go ya ka molawana 5 le mpshafatšo ya dilaesense
7. Boipelaetšo kgahlanong le sepheto sa Khansele
8. Kgopelo ya ngwadišo ya sedirišwa sa bongaka goba IVD
9. Tshedimošo yeo e swanetšego go tšweletšwaretšisetareng ya didirišwa tša bongaka goba di-IVD
10. Phetošo ya retšisetara ya didirišwa tša bongaka le di-IVD
11. Magoro a didirišwa tša bongaka le di-IVD
12. Setifikeiti sa ngwadišo
13. Dikarolwana le diripana

14. Tshenyo ya sedirišwa sa bongaka le IVD
15. Mokgwa wa go tšea dišupo ge go dirwa nyakišišo, setifikeiti seo se tligelo go newa le pego ya dipelo phetleko
16. Maitshwaro a teko ya bongaka le dinyakišišo tša bongaka
17. Pego ya tiragalo ye kgahlanong le hlokomelo
18. Nyakišišo
19. Melato le dikotlo
20. Kobamelo ya dinyakwa
21. Papatšo ya sedirišwa sa bongaka goba IVD
22. Phethagaletšo ya setlankana sa sedirišwa sa bongaka goba IVD
23. Ditaetšo tša tirišo ya sedirišwa sa bongaka
24. Ditaetšo tša Tirišo ya IVD
25. Didirišwa tša bongaka tše di dirilwego ka kgethego
26. Rekhoto ya didirišwa tša bongaka tše di tsenyegago le didirišwa tša bongaka tše di dirilwego ka kgethego
27. Dipeakanyetšo tša nakwana- motšweletši wa go hloka laesense, mophatlalatši le rakgwebokgolo
28. Dipeakanyetšo tša nakwana- didirišwa tša bongaka tše di sa ngwadišwago le di-IVD
29. Thaetlele ye kopana

1. DIHLALOŠO

Mo melawaneng ye lentšu goba mmolelwana wo o hlalošitšwego Molaong o na le hlalošo ye e neilwego ntle le ge tshwaragano e laetša ka tsela ye nngwe-

"tiragalo ye kgahlanong" malebana le sedirišwa sa bongaka goba IVD e ra kgonagalo ya diphošo goba dipolelo tša sedirišwa sa bongaka goba IVD goba mathata a tirišo ya goba pelo yeo e sa letelwago ye e sepelelanago le tirišo ya sedirišwa sa bongaka goba IVD ao a ka diragalago goba ao a hlalago tshenyo ya go ya go ile, kgobalo goba lehu go modiriši wa profešene goba modiriši yo e lego molwetši;

"ka ge go laetšwe ke Khansele" e ra ka ge go laetšwe ke Khansele ya Taolo ya Dihlare go methalohlahli yeo e gatišitšwego *Kuranteng ya Mmušo* ka nako le nako;

"moemedi yo dumeletšwego" o ra motho, yo a dulago mo Rephabliki ya Afrika Borwa, yo a -

- (a) nago le mošomo wa go emela motšweletši, moromela ditšwantle, mophatlalatši, rakgwebokgolo, morekiši goba mophethagaletša tirelo mo Rephabliki;
- (b) dirago bakeng sa motšweletši, moamogela ditšwantle, mophatlalatši, rakgwebokgolo, morekiši goba mophethagaletša tirelo ya mošomo wo itšego malebana le ditlamego tša gagwe mme yo laesense ya tšweletšo, laesense ya phatlalatšo, laesense ya kgwebokgolo goba setifikeiti sa ngwadišo se dirwago ka leina la gagwe; le
- (c) yo a nago le maikarabelo a dintlha ka moka tša sedirišwa sa bongaka goba IVD, go akaretšwa tiragatšo, boleng, polokego le kobamelo ya dipeelano tša ngwadišo, teko ya bongaka goba dinyakišišo tša bongaka;

"nomoro ya sehlopha," "nomoro ya karolo" goba "palotatlano" goba "palotaolo" "nomoro ya mohuta" e ra nomoro ye kgethegilego goba dinoromo tše kopantšwego goba dikhoutu tše di neilwego karolo goba sehlopha goba selomaganyo sa sedirišwa sa bongaka se se kgethegilego bakeng sa "palotaolo", goba mananeotirišo a khomphuthara bakeng sa "nomoro ya mohuta" ka motšweletši;

"selo sa paolotši" se ra selo se se hwetšwego mothong, phoofolong goba sepheding;

"ngwakopolokelo" e ra ngwako wa dithoto le tiragatšo wa laesense ya go ya ka karolo 19 ya *Customs and Excise Act, 1964* (Molao 91 wa 1964);

"nyakišišo ya bongaka goba teko ya bongaka" e ra nyakišišo mabapi le sedirišwa sa bongaka goba IVD bakeng sa tirišo go batho le diphoofolo yeo e akaretšago batho goba diphoofolo mme yeo e ikemišeditšego, ka phetleko le tekolo ya tshedimošo ya bongaka ye malebana le sedirišwa sa bongaka, go hwetša le go netefatša polokego goba tiragatšo ya bongaka ya sedirišwa sa bongaka goba IVD ge e dirišwa go ya ka maikemišetšo ke motšweletši;

"nyakišišo ya tiragatšo ya bongaka ya IVD" e ra nyakišišo yeo e dirwago go bona goba go netefatša tiragatšo ya bongaka ya IVD;

"sedirišwa sa kopanyo" se ra sedirišwa sa bongaka, se se kopanyago, bjalo ka karolo ye bohlokwa, selo seo se ka tšewago bjalo ka sehlare, ge se dirišwa ka bosona, mme seo se dirago bjalo ka sethuši sa sedirišwa sa bongaka mmeleng wa motho;

"phetleko ya kobamelo" e ra hlahlobo ya lenaneo ya bohlatse yeo e dirilwego le ditshepetšo tšeo di diragaditšwego ke motšweletši, go laetša gore sedirišwa sa bongaka goba IVD e bolokegile le gore e dira gabotse mme le gore sedirišwa sa bongaka goba IVD e fihlelela Molao ye Bohlokwa ya Polokego le Tiragatšo ya Didirišwa tša Bongaka goba di-IVD bjalo ka ge go laeditšwe ke Khansele;

"mokatlo wa phetleko ya kobamelo" o ra mokgatlo goba sehlengwa sa molao goba motheo wo mongwe wa molao, wa segae goba boditšhabatšhaba, wo o netefaditšwego ke SANAS goba mokgatlo wa boditšhabatšhaba wo o amogetšwego ke Khansele bjalo ka wo o kgonago go diragatša

phetleko, netefatšo, hlahlobo goba go nea setifikeiti, ka mo go swanetšego, sa didirišwa tša bongaka goba di-IVD, pele di rekišwa ke batšweletši, go ya ka tekanyetšo yeo e laolwago ke Khansele;

"setifikeiti sa phetleko ya kobamelo" se ra setifikeiti seo se neilwego, ke Mokgatlo wa Phetleko ya Kobamelo, go laetša kobamelo le Melao ye Bohlokwa ya Polokego le Tiragatšo bakeng sa Sedirišwa sa Bongaka le dinyakwa tša IVD;

"sedirišwa sa bongaka se se dirilwego ka kgethego" se ra sedirišwa sa bongaka-

- (a) se se dirilwego go ya ka taetšo goba taelo ye e neilwego ke motho yo a dumeletšwego go dira seo ka lebaka la boithutelo;
- (b) se se dirilwego go ya ka sebopego se se itšego;
- (c) se se nago le maikemišetšo a tirišo ya motho yo itšego fela; gape
- (d) se se kgethollago didirišwa tšeo di tšweleditšwego ka bontšhi tše di hlokago phetošo fela go fihlelela dinyakwa tše itšego tša modiriši wa profeshenale;

"pego ya kobamelo" e ra ditshepetšo tšeo ka tšona motšweletši a netefatšago ebile a begago gore kgopelo ya tsela ya boleng yeo e dumeletšwego bakeng sa sebopego, tšweletšo le hlahlobo phethagatšo ya ditšweletšwa tše malebana, go ya ka dinyakwa tša Khansele, tšeo di tilego go fetlekwa le go nyakišišwa, di fihleletšwe.

"mophatlalatši" o ra motho goba mokgatlo wo o -

- (a) amogelago ditšwantie goba o romelagontle sedirišwa sa bongaka goba IVD, yeo e lego ngwadišong ya didirišwa tša bongaka goba ngwadišong bakeng sa di-IVD phethagatšong ya tšona, phuthelo ka pono ya gore sedirišwa sa bongaka se rekišwe ka leina la motho goba mokgatlo; le
- (b) rekišago sedirišwa sa bongaka goba IVD go profeshenale ya tša maphelo, sehlengwa sa maphelo, rakgwebokgolo goba modiriši;

"melao ye bohlokwa" e ra dinyakwa tše malebana le polokego le dibopego tša tiragatšo tša didirišwa tša bongaka le di-IVD tšeo di laolwago ke Khansele;

"letšatšikgwedi la mafelelo" le ra letšatšikgwedi la mafelelo leo sedirišwa sa bongaka goba IVD e swarago dilo tšeo di hlalošitšwego setlankaneng, dikagare tšeo di ka fetogago morago ga phelelo ke nako, mme le letšatšikgwedi leo morago ga lona sedirišwa sa bongaka goba IVD e ka se rekišetšwe setšhaba goba e ka se dirišwe;

"mohuta" le ra sedirišwa sa bongaka goba IVD yeo e nago le mohuta wo swanago wa sedirišwa sa bongaka seo se hwetšagalago ka mehutahuta le bokima bjo bo fapafapanego;

"sehlopha" se ra sedirišwa sa bongaka goba IVD yeo e nago le kgoboketšo ya didirišwa tša bongaka goba di-IVD tša go swana le sephuthelwa sa tshepetšo, boroto ya tshepetšo, tsela goba khiti

ya tshepetšo, tšeo di phuthetšwego mmogo bakeng sa mohola wa maikemišetšo wo itšego mme e rekišwa ka tlase ga leina le tee;

"moswari wa setifikeiti sa ngwadišo" e ra motho yoo setifikeiti se neilwego ka leina la gagwe mme yo a nago le maikarabelo a dintlha ka moka tša sedirišwa sa bongaka goba IVD, go akaretšwa tiragatšo, boleng, polokego le kobamelo ya dipeelano tša ngwadišo;

"sedirišwa seo se tsenywago" se ra sedirišwa sa bongaka, go akaretšwa sedirišwa sa bongaka seo se hupiwago ka boripana goba ka botlalo, seo -

- (a) go nago le maikemišetšo a go se tsenya mmeleng wa motho goba, go bea bakeng bokagodimo bja epitheliale goba bokagodimo bja leihlo ka puo ; le
- (b) seo se ikemišeditšego go dula lefelong le tee bakeng sa matšatši a 30 morago ga tshepetšo;

"maikemišetšo a mohola" a ra maikemišetšo a tirišo goba mohola wo sedirišwa sa bongaka goba IVD a lego, ka moo go lego ka gona, go ya ka tshedimošo yeo e neilwego ke motšweletši goba moemedi yo a dumeletšwego setlankaneng, ditaetšong tša tirišo le matherialeng wa dipapatšo;

"IVD" ("phekolo ka *in-vitro* ") e ra sedirišwa sa bongaka, le ge se dirišwa ka bo sona goba le se sengwe, seo motšweletši wa dihlahlobo tša *in vitro* a nago le maikemišetšo a go se diriša ka dišupo tšeo di tšerwego mmeleng wa motho bakeng sa go phethagaletša tshedimošo ya meholo ya phekolo, tekolo goba tshepelantšho;

"motho yo a sa rutegago" e ra motho yo a hlokago katišo ya semmušo boithutelong bjo itšego;

"tšweletšo" e ra ditiragatšo tše di akaretšago dibopego, theko ya matheriale, ditaetšo tša tlhabollo, tšweletšo, hlamo, kago, tshepetšo, tshepetšo gape, tokollo, phuthelo, phuthelo gape, ditlankana le kaonafatšo ya sedirišwa sa bongaka goba IVD, ka moo go lego ka gona, mme e akaretša go dira kgoboketšo ya didirišwa tša bongaka goba di-IVD, le ditšweletšwa tše dingwe ge go kgonagala, gammogo le, bakeng sa mohola wa bongaka go ya ka netefatšo ya boleng, ditaolo tše malebana;

"motšweletši" o ra -

- (a) motho goba mokgatlo wo o nago le maikarabelo a sebopego, tšweletšo, phuthelo le ditlankana tša sedirišwa sa bongaka goba IVD pele e tsenywa marakeng bakeng sa thekišo ka tlase ga leina la motho goba mokgatlo, goba leineng la feme goba khamphani, go sa kgathalatšege gore ditiragatšo tše di dirwa ke motho yoo ka boyena goba ke motho yo mongwe bakeng sa gagwe. goba
- (b) motho yo mongwe le yo mongwe yo a agago, phuthelago, sepetšago gape, kaonafatšago goba a dirago ditlankana tša setšweletšwa goba ditšweletšwa tšeo di setšego di dirilwe goba a phethagaletšago mohola wa tšona bjalo ka sedirišwa sa bongaka goba IVD, ka maikemišetšo a go di rekiša ka tlase ga leina la motho goba mokgatlo, ntle le motho yo a

agago goba a fetošago didirišwa tša bongaka goba di-IVD tšeo di šetsego di rekišetšwa mohola wa tšona go baiwetši;

"leina le le sa nepagalago" le ra setlankana sa sedirišwa sa bongaka sa bofora, sa fošagalo, phošo goba seo se palelwago ke go phethagaletša tshedimošo ka moo go hlokegago;

"phetošo" malebana le sedirišwa sa bongaka goba IVD e ra-

(a) phetošo efe goba efe ye e bonalago sedirišweng sa bongaka goba IVD;

(b) phetošo efe goba efe bakeng sa sedirišwa sa bongaka goba IVD, moo phetošokgolo e ka akaretšago-

(i) tshepetšo ya tšweletšo;

(ii) tsenyotirišo goba didirišwa;

(iii) magato a netefatšo ya boleng ao a dirišetšwego go laola boleng le hlweko ya sedirišwa sa bongaka goba IVD; goba

(iv) phetošo ya matheriale o o dirišetšwego tšweletšong, sebopego sa sedirišwa sa bongaka goba IVD, go akaretšwa tiragatšo ya sona le dibopego, melao ya tiragatšo le ditaetšo tša matheriale, setlogo sa enetši, mananeotirišo a khomphuthara goba dilomaganyo le maikemišetšo a tirišo a sedirišwa sa bongaka goba IVD;

(c) tirišo efe goba efe ya mathomo goba ya koketšego, tlaleletšo goba phumolo ya taetšo ye kgahlanong ya sedirišwa sa bongaka goba IVD; le

(d) phetošo efe goba efe nakong yeo e dirišwago go hwetša letšatšikgwedi la mafelelo;

"teko ya molwetši ye kgauswi" goba **"lefelo la teko"** le ra teko yeo e dirwago ka ntle ga laboratori ke mošomi wa tša maphelo efela le ge e se mošomi wa laboratori, ka kakaretšo kgauswi le, goba thoko ga, molwetši;

"maina" e ra hlalošo yeo e tiwaelegilego go ya ka Maina Dirišwa tša Bongaka a Lefase ka bophara yeo e nago le dibopego tša go swana le maikemišetšo a tirišo;

"motho" e ra motho le mokgatio;

"radiešene" e ra enetši ya mohuta wa elektromeknethiki goba tša akhustiki;

"kaonafatšo" malebana le sedirišwa sa bongaka goba IVD e ra karolwana goba botlalo bja sedirišwa sa bongaka goba IVD e agiwe gape, e tsentšwe didirišwa gape, e fetošitšwe goba e tšošološitšwe go sa kgathalatšege gore naa ke ka tirišo ya dikarolo tša sedirišwa sa bongaka se se tee goba tše ntšhi tše didirišwego tša mohuta wo tee, bakeng sa go hlola sedirišwa sa bongaka goba IVD yeo e dirišetšwego mohola wa mathomo ke motšweletši wa mathomo wa sedirišwa sa bongaka sa mathomo goba IVD, mme ntle le kgethollo go kakaretšo ya tša pele, kaonafatšo ya sedirišwa sa

bongaka e ka akaretša tiro efe goba efe goba ka moka ga ditiro tše di latelago, go akaretšwa, efela di sa felele ka, tokišo, phetošo, kaonafatšo ya mananeotirišo a Khomphuthara goba hatewee ya khomphuthara le peobakeng ya dikarolo tše di senyegilego ka dikarolo tšeo di dumelletšwego tirišo ke motšweletši wa mathomo, di dirigatšwa ka tsela yeo e sepelelanago le ditaetšo tša ditšweletšwa le ditshepetšo tša tirelo tšeo di hlalošitšwego ke motšweletši wa mathomo bakeng sa mohuta wa sedirišwa seo ntle le go fetoša tiragatšo ya sedirišwa seo se phethagaleditšwego, ditaetšo polokego goba maikemišetšo a tirišo bjalo ka ge go hlalošitšwe ngwadišong ya sona ya mathomo;

"IVD yeo e dirisetšwago nyakišišo fela" ("RUO IVD") e ra IVD ya setlankana sa taetšo ya "tirišo ya nyakišišo fela" le "bakeng sa tirišo ya dinyakišišo fela" mme ga se ya swanela go dirisetšwa meholo ya phekolo ya bongaka;

"tshhepetšo gape" e ra tiragatšo yeo e diragatšwago sedirišweng seo se dirišitšwego bakeng sa go kgontšha tirišo gape ya sona go akaretšwa hlwekišo, tlošotwatsi le ditshepetšo tše malebana gammogo le diteko le tšošološo ya polokego ya sethekgeniki le tirišo ya sedirišwa sa bongaka;

"teko ya bowena" e ra teko yeo e dirwago ke motho yo a sa rutegago;

"tirišo ga tee" go ya ka sedirišwa sa bongaka e ra tirišo ga tee ya sedirišwa sa bongaka mothong goba IVD sešupong mo nakong ya tshhepetšo ye tee mme morago ga fao sedirišwa sa bongaka goba IVD e a lahlwa ebile ga e dirišwe gape;

"Molao" o ra *Medicines and Related Substances Act, 1965* (Molao 101 wa 1965);

"modiriši" e ra motho goba mokgatlo woo o dirišago sedirišwa sa bongaka goba IVD; le

"rakgwebokgolo" o ra morekiši yo a rekago didirišwa tša bongaka goba di-IVD go batšweletši goba baphatlalatši mme a direkišetša mabenkele.

2. Mokgwa le dipeelano bakeng sa tumello ya dithentara tša boditšhabatšhaba

- (1) Mmušo o ka dira thentara ya sedirišwa sa bongaka gova IVD ka boditšhabatšhaba ge sedirišwa sa bongaka goba IVD—
 - (a) e ka hwetšwa ka theko ye tlase mo ntle ga Rephabliki; goba
 - (b) e le, go ya ka Tona, ye bohlokwa bakeng sa maphelo a bosetšhaba.
- (2) Sedirišwa sa bongaka goba IVD e ka se hwetšwe ka thentara ya boditšhabatšhaba ntle le ge sedirišwa sa bongaka goba IVD e ngwadišitšwe.

3. Didirišwa tša bongaka le di-IVD tša ditšwantle mo Rephabliki

- (1) Motho ga se a swanela go romela setšwantle sa sedirišwa sa bongaka goba IVD mo gare ga Rephabliki ka go se tsenya ka:
 - (a) Boemafofane bja Boditšhabatšhaba ba Toropo ya Kapa;
 - (b) Boemafofane bja Port Elizabeth goba boemakepe;
 - (c) Boemafofane bja Boditšhabatšhaba ba King Shaka goba boemakepe ba Durban; goba
 - (d) Boemafofane bja Boditšhabatšhaba ba OR Tambo
- (2) Ntle le molawana 3(1), didirišwa tša bongaka tše di dirišitšwego goba di-IVD di ka romelwa ke motšweletši bakeng sa meholo ya tirelo, tokišo, kaonafatšo goba hlokomelo.
- (3) Motho a ka romela setšwantle sa sedirišwa sa bongaka goba IVD fela ge motho yoo-
 - (a) a na le laesense go ya ka karolo 22C(1)(b) ya Molao go phethagaletša ditšwantle tša didirišwa tša bongaka goba di-IVD; gape
 - (b) bakeng sa didirišwa tša bongaka tseo di sa ngwadišwago goba di-IVD, a dumelletšwe ke Khansele go phethagaletša ditšwantle tša didirišwa tša bongaka tseo di sa ngwadišwago goba di-IVD.

4. Thomelo ya didirišwa tša bongaka goba di-IVD mo Rephabliki

- (1) Didirišwa tša bongaka le di-IVD tše di romelwago mo Rephabliki di swanetše go-
 - (a) ge di le mo Rephabliki, bolokwa lefelo polokelong le le tswetšwego leo le ngwadišitšwego le Khansele; le
 - (b) se fetošwe ge di le lefelo polokelong le le tswetšwego ntle le ge Khansele e neile tetla.
- (2) Lefelo polokelo le le tswetšwego leo le hlalošitšwego go molawana (1) le swanetše go obamela dipeelano tša lefelo polokelo tseo di beilwego ke Khansele.

5. Laesense ya tšweletšo, ditšwantle, diromelwante, goba go dira bjalo ka mophatlalatši goba rakgwebokgolo ya didirišwa tša bongaka goba di- IVD

- (1) Motšweletši, rakgwebokgolo goba mophatlalatši yo a hlalošitšwego fo karolo 22C(1)(b) ya Molao o swanetše-
- (a) pele ga thomo ya kgwebo-
- (i) go dira kgopelo go Khansale bakeng sa -
- (aa) laesense ya motšweletši ya go tšweletša, go amogela ditšwantle goba diromelwante tša didirišwa tša bongaka goba di-IVD; goba
- (bb) laesense ya mophatlalatši ya go amogela ditšwantle, diromelwante le phatlalatšo ya didirišwa tša bongaka goba di-IVD; goba
- (cc) laesense ya kgwebokgolo go dira bjalo ka rakgwebokgolo wa didirišwa tša bongaka goba di-IVD;
- (ii) go thwala le go kgetha moemedi yo a dumeletšwego yo a swanetšego go dula mo Afrika Borwa-
- (aa) go nna le maikarabelo go Khansale bakeng sa kobamelo ya Molao; le
- (bb) go laola tšweletšo, phatlalatšo, kgwebokgolo le thekišo ya didirišwa tša bongaka goba di-IVD.
- (b) go romela kgopelo ya laesense go Mongwadiši, godimo ga foromo yeo e dumeletšwego ebile e phethagaleditšwego ke Khansale;
- (c) bjalo ka karolo ya kgopelo, ka mokgwa wa tokomane a romele bohlatse bja-
- (i) dintlha tša mong wa kgwebo;
- (ii) dintlha tša moemedi yo a dumeletšwego; le
- (iii) setifikeiti sa Tsela ya Taolo ya Boleng bakeng sa didirišwa tša bongaka le di-IVD bjalo ka ge go laolwa ke Khansale;
- (d) laetša, bjalo ka ge go laolwa ke Khansale, didirišwa tša bongaka goba di-IVD goba sehlopha sa didirišwa tša bongaka goba di-IVD tše di swanago tšeo di swanetšego go tšweletšwa, go amogelwa, go romelwante goba go phatlalatšwa le go rekišwa; le
- (e) go lefela tefelo ye swanetšego.

- (2) Mongwadiši a ka nea motho yo a hlalošitšwego go molawana (1) tsebišo ya lengwalo go romela ditokomane goba tshedimošo ka moo Khansele e hlokago, mo nakong ye e kwagalago bjalo ka ge go hlalošišwe tsebišong.
- (3) Khansele e ka dira phetleko ya lefelo la kgwebo le le ngwadilwego kgopelong, moo go hlokegago.
- (4) Ge Khansele e kgotsofale gore-
- (a) motho yo hlalošitšwego go molawana (1) o obamela dinyakwa tše di beilwego;
 - (b) kgopelo ya laesense-
 - (i) ya go tšweletša, go amogela diromelwantle goba ditšwantle tša didirišwa tša bongaka goba di-IVD; goba
 - (ii) go dira bjalo ka mophatlalatši; goba
 - (iii) go dira bjalo ka rakgwebokgolo wa didirišwa tša bongaka goba di-IVD go obamela dinyakwa tše di beilwego; le
- Moemedi yo a dumeletšwego o kgona go phethagaletša bohlatse bjo bo netefaditšwego Tseleng ya Taolo ya Boleng bjalo ka ge go laetšwe ke Khansele, Khansele e swanetše go dumelela, ka dipeelano goba ntle natšo, kgopelo mme e nee motho laense.
- (5) Mongwadiši o swanetše-
- (a) go lota retšisetara ya sepheri bakeng sa legoro le lengwe le le lengwe la laesense yeo e hlalošitšwego go molawana (1)(a)(i); le
 - (b) go tsenya noromo ya laense, leina la mong wa laesense le aterese ya gagwe ya bodulo goba poso, ka gare ga retšisetara.
- (6) Go sa setšwe botelele bja nako bja go šoma ga laesense, mong wa laesense o swanetše go lefela tefišo ya ngwaga ya go tšwelapele ga ngwadišo go ya ka moo Khansele e laetšego.
- (7) Mong wa laesense o swanetše go tsebiša Mongwadiši ka tsela ya lengwalo ka ga phetošo ya dintlha dife goba dife tšeo di rometšwego kgopelong goba tše di loketšwego retšisetareng, tšeo di diregago morago ga kabelo ya laesense.
- (8) Tsenyo ka gare ga retšisetara yeo go laetšwego ka bohlatse bja phethaga go Khansele, gore e dirilwe ka phošo goba ka bofora goba ka tiase seemo se se sa dumelelwago ke Molao, e ka phumolwa ke mongwadiši.
- (9) Motho yoo phumolo ya tsenyo yeo e dirilwego ka leina la gagwe bjalo ka ge go hlalošitšwe go molawana (8), o swanetše go tsebišwa ka ga phumolo mme setifikeiti

seo se neilwego malebana le ngwadišo se swanetše go bonwa bjalo ka se se phumotšwego go thoma ka letšatšikgwedi leo tsebišo e neilwego.

(10) Khansele e ka, go ya ka molawana (11), laela mongwadiši gore a tloše leina la mong wa laesense mo retšisetareng ge-

- (a) mong wa laesense a sa obamele Molao goba dipeelano tša laesense;
- (b) moemedi yo dumeletšwego a palelwa ke go laola tšweletšo le phatlalatšo, kgwebokgolo goba thekišo ya didirišwa tša bongaka goba di-IVD; goba
- (c) mong wa laesense a palelwa ke go romela mabaka ka tsela ya lengwalo mo nakong yeo e beilwego tsebišong yeo e hlalošitšwego go molawana (11).

(11) Pele e laela Mongwadiši go phumola leina la mong wa laesense retšisetareng, Khansele e swanetše go-

- (a) nea tsebišo ya maikemišetšo a yona a go phumola leina la mong wa laesense mo retšisetareng mme le go tswalela kgwebo ya mong wa laesense; le
- (b) go laletša mong wa laesense go romela mabaka ka tsela ya lengwalo, mo matšatšing a 21 a tsebišo, gore ke ka lebaka la eng laesense e sa swanela go phumolwa retšisetareng mme le mabaka a gore kgwebo e se tswalelwe.

6. Nako ya go šoma ga laesense le mpshafatšo ya laesense

- (1) Laesense yeo e neilwego go ya ka molawana 5 e a šoma bakeng sa mengwaga ye mehlano(5) go thoma ka letšatšikgwedi ka kabo.
- (2) Laesense yeo e hlalošitšwego go molawana (1) e ka mpshafatšwa ka kgopelo go Khansele.
- (3) Kgopelo ya mpshafatšo ya laesense e swanetše-
 - (a) go ba le tshedimošo goba ditokomane tše di hlalošitšwego go molawana 5(1)(c), ka moo go lego ka gona;
 - (b) go sepela le tefelo ye e beilwego; gape e
 - (c) dirwe mo matšatšing a 90 pele ga letšatšikgwedi la mafelelo la laesense yeo e šomago.

7. Boipelaetšo kgahlanong le sepheto sa Khansele

- (1) Motho yo a nago le ngongorego ka sepheto sa Khansele a ka, ka ge go hlalošitšwe go karolo 24 ya Molao, dira boipelaetšo kgahlanong le sepheto, ka tsela ya lengwalo, mo matšatšing a 30 morago ga go tsebišwa ka sepheto sa Khansele.
- (2) Tsebišo ya boipelaetšo e swanetše go romelwa go Modulasetulo wa Khansele, e lebišitšwe go Mongwadiši, Medicines Control Council, Private Bag X828, Pretoria, 0001
- (3) Maphodisa ao a tšweletšego go molawana (2) a swanetše go tšweletša ka tsela yeo ekwešišegago ebile yeo e kwagalago gore mabaka a boipelaetšo ke afe.
- (4) Mongwadiši, mo matšatšing a 30 a khwetšo ya tsebišo boipelaetšo, ntle le go ba gona ga baemedi, o swanetše go kopana le moipelaetši mme a leke go rarolla bothata.
- (5) Ge bothata bo sa rarollwa go ya ka molawana (4), moipelaetši, mo matšatšing a 30 a go tsebišwa ke Mongwadiši ka ga palelo ya go rarolla bothata, mme morago ga tefelo ya tefišo ye e beilwego, a ka kgopela Tona go phethagaletša komiti ya boipelaetšo.
- (6) Komiti ya boipelaetšo -
 - (a) e swanetše go laetša tshepetšo ya dikopano tša yona;
 - (b) ge e bona hlokego, e ka nyaka bohlatse bja molomo goba ngangišano goba ya bitša motho ofe goba ofe yo-
 - (i) go ya ka boikgopolelo bja yona, a ka kgonago go nea tshedimošo mabapi le seemo sa boipelaetšo; goba
 - (ii) e dumelago gore o na le tokomane yeo e nago le khuetšo morerong wa boipelaetšo, go tšwelela pele ga komiti ka nako le lefelong leo le laeditšwego ditagafaleng, bakeng sa go botšišwa dipotšišo goba go tšweletša tokomane;
 - (c) ge e bitša bohlatse bja molomo goba ngangišano, e swanetše go, -
 - (i) laetša letšatšikgwedi, nako le lefelo la boipelaetšo mme e swanetše go hlaloša tše ka tsela ya lengwalo go moipelaetšo le Khansele; gape le
 - (ii) go sepetša keno ya go, goba amogela keno gotšwa go, motho ofe goba ofe yo a bitšwago bjalo ka hlatse boipelaetšong.
- (7) Motho yo a tšwelelago pele ga komiti ya boipelaetšo a ka emelwa ke mmoleledi.

- (8) Komiti ya boipelaetšo e swanetše go eleletša boipelaetšo mme e dire sepheto mo matšatšing a 30 go tloma ka letšatšikgwedi la kopano ya mathomo ya go theeletša boipelaetšo.

8. Kgopelo ya ngwadišo ya sedirišwa sa bongaka goba IVD

- (1) Motho yo a dulago ebile a dira kgwebo mo Rephabliki a ka dira kgopelo ya ngwadišo ya sedirišwa sa bongaka goba IVD.
- (2) Kgopelo ya ngwadišo ya sedirišwa sa bongaka goba IVD e swanetše go akaretša dintlha tša moemedi yo a dumeletšwego mo Afrika Borwa yo a nago le maikarabelo a poledišano le Khansele.
- (3) Kgopelo ya ngwadišo ya sedirišwa sa bongaka goba IVD e swanetše go dirwa foromong ye e swanetšego yeo e hwetšagalago gotšwa go Mongwadiši mme e swanetše go sepela le-
- (a) foromo ye e tladišwego;
 - (b) setlankana seo se beilwego sa sedirišwa sa bongaka goba IVD, ge e hlokega;
 - (c) ditaelo tša tirišo ya sedirišwa sa bongaka goba IVD;
 - (d) mo go hlokegago,
 - (i) ngwalollo ya laesense ya motšweletši goba laesense ya mophatlalatši gammogo le setifikeiti sa phetleko ya kobamelo sa Tsela ya Taolo ya Boleng bakeng sa hlango ya segae ya sedirišwa sa bongaka, bjalo ka ge go laetšwa ke Khansele; gape
 - (ii) ngwalollo yeo e netefadišwego ya setifikeiti sa hlahlobo ya kobamelo maemong a boleng, bjalo ka ge go laetšwa ke Khansele, bakeng sa sedirišwa sa bongaka goba IVD yeo e swanetšego go ngwadišwa, mme yeo e newago ke Mokgatlo wa Phetleko ya Kobamelo;
 - (e) tshedimošo ye nngwe ka moo Khansele e ka laetšago; le
 - (f) tefišo ya go dira kgopelo.
- (4) Tshedimošo yeo e hlalošitšwego go molawana (3) e swanetše go ba ka polelo ya seisimane.
- (5) Foromo ya kgopelo yeo e hlalošitšwego go molawana (3)(a) e swanetše go ba le tshedimošo ye e latelago:
- (a) Dintlha tša motho yo e tiilego go ba mong wa setifikeiti sa ngwadišo:
 - (i) Leina;

- (ii) Aterese ya kgwebo;
 - (iii) Aterese ya poso;
 - (iv) Nomoro ya mogala;
 - (v) Nomoro ya fekese, ge e hlokega;
 - (vi) Aterese ya emeile; le
 - (vii) Dintlha tša boikgokaganyo tša baemedi bao ba dumeletšwego bao ba hlalošitšwego go molawana (2).
- (b) Dintlha tša sedirišwa sa bongaka goba IVD:
- (i) Leina le sehlopha goba leina la tše di swanago, sebopego le mohuta, moo go kgonegago;
 - (ii) maikemišetšo a mohola goba tirišo;
 - (iii) magoro le seemo sa ngwadišo bolaoding bjo bo amogegago ka ntle ga Rephabliki, bjalo ka ge go laeditše Khansele, le tšhišinyo ya magoro mo Rephabliki;
 - (iv) khoutu ya tsela ya maina;
 - (v) bakeng sa sedirišwa sa kopanyo, leina le palo ya dilo tša šetule goba dilo tša paolotši;
 - (vi) leina le aterese ya bodulo ya motšweletši wa mathomo; le
 - (vii) leina le aterese ya bobulo ya mafelo a nyakišišo ya tša bongaka, mo go hlokegago.
- (6) Sedirišwa sa bongaka goba IVD, yeo e direlwago kgopelo ya ngadišo, e swanetše go obamela Melao ye Bohlakwa ya Polokego le Tiragatšo ya Didirišwa tša Bongaka tše di akaretšago dinyakwa tša boleng, polokego le tiragatšo, ka ge Khansele e laeditše.
- (7) Kgopelo ya ngwadišo ya sedirišwa sa bongaka e swanetše go sepela le pego ya kobamelo ka moemedi yo a dumeletšwego ka moo Khansele e laeditšego.
- (8) Kgopelo e swanetše go dirwa go ya ka sedirišwa sa bongaka goba IVD ye nngwe le ye nngwe, goba sehlopha, tše swanago goba phetošo ya sedirišwa sa bongaka, ka moo go laeditšwego ke Khansele.

- (9) Ge sedirišwa sa bongaka goba IVD yeo e direlwago ngwadišo e nwadišitšwe le mokgatio mokgatio wa taolo ka ntle ga Rephabliki, tshedimošo ye e latelago mabapi le sedirišwa sa bongaka goba IVD e swanetše go sepela le kgopelo:
- (a) Ngwalollo ye e netefaditšwego ya ngwadišo goba tumello ya pele ga go išwa marakeng, mo go hlokegago;
 - (b) ditaetšo tša dirišo, mo go swanetšego;
 - (c) dipeelano tša ngwadišo; le
 - (d) tshedimošo efe goba efe yeo e laetšwago ke Khansale.

9. Tshedimošo yeo e swanetšego go tšwelela retšisetareng ya didirišwa tša bongaka goba di-IVD

Retšisetara ya didirišwa tša bongaka goba di-IVD e swanetše, mabapi le sedirišwa sa bongaka goba IVD, go ba le tshedimošo ye e latelago:

- (a) leina le sehlopha goba tša go swana le mohuta, moo go hlokegago, tša sedirišwa sa bongaka goba IVD;
- (b) nomoro ya ngwadišo yeo e neilwego sedirišwa sa bongaka goba IVD;
- (c) bakeng sa sedirišwa se se kopantšwego, leina le palo ya dilo tša šetule goba dilo tša paolotši tše di lego ka gare ga sedirišwa sa bongaka;
- (d) maikemišetšo a mohola goba tirišo ya sedirišwa sa bongaka goba IVD;
- (e) leina la mong wa setifikeiti sa ngwadišo;
- (f) leina le aterese ya motšweletši wa mathomo;
- (g) letšatšikgwedi la ngwadišo ya sedirišwa sa bongaka goba IVD;
- (h) dipeelano tša ngwadišo ya sedirišwa sa bongaka goba IVD;
- (i) legoro la sedirišwa sa bongaka goba IVD; le
- (j) khoutu ya tsela ya maina yeo e neilwego sedirišwa sa bongaka goba IVD.

10. Phetošo ya Retšisetara ya sedirišwa sa bongaka le IVD

- (1) Mong wa setifikeiti sa ngwadišo a ka romela go Mongwadiši, kgopelo foromong, bjalo ka ge Khansele e laeditše, go fetoša tsenyo ye e dirilwego didirišweng tša bongaka goba ngwadišo ya di-IVD.
- (2) Kgopelo ye e hlalošitšwego go molawana (1) e swanetše go sepela le tefelo yeo e beilwego, mme e swanetše go sepela le tshedimošo ye e latelago:
 - (a) nomoro ya ngwadišo ya sedirišwa sa bongaka goba IVD;
 - (b) leina le aterese ya kgwebo ya mong wa setifikeiti sa ngwadišo le moemedi yo a dumeletšwego;
 - (c) pego ka moemedi yo a dumeletšwego gore tshedimošo ye e neilwego e phethagetše ebile e nepagetše;
 - (d) dintlha tša phetošo yeo e kgopetšwego;
 - (e) nomoro ya laesense ya tšweletšo ya motšweletši goba nomoro ya laesense ya phatlalatšo ya mophatlalatši; le
 - (f) tshedimošo ye nngwe yeo e laetšwago ke Khansele.

11. Magoro a didirišwa tša bongaka le di-IVD

- (1) Tše latelago ke magoro a didirišwa tša bongaka le di-IVD:

- | | | |
|-----|----------|----------------------------|
| (a) | Legoro A | -Kotsi ye tlase; |
| (b) | Legoro B | -Kotsi ye tlase-bogareing; |
| (c) | Legoro C | -Kotsi ye bogareng-godimo; |
| (d) | Legoro D | -Kotsi ye godimo. |

moo kotsi e sepelelanago le molwetši, modiriši goba maphelo a setšhaba.

- (2) Didirišwa tša bongaka ntle le didirišwa tša bongaka tše di dirilwego ka kgethego le di-IVD di swanetše go ngwadišwa le Khansele go ya ka ditsebišo pele di ka rekišwa goba tša dirišwa mo Rephabliki.
- (3) Khansele e swanetše go laetša magoro a didirišwa tša bongaka le di-IVD go ya ka melao ya magoro.

- (4) Moo legoro la sedirišwa sa bongaka le sa tsebege mme le se wela magorong a go feta le le tee, goba magareng ga magoro, Khansele e swanetše, morago ga go latela melao ya magoro, go tsenya sedirišwa sa bongaka goba IVD legorong la kotsi ya godimo ya magoro a kotsi.
- (5) Khansele e swanetše go eleletša magoro a sedirišwa sa bongaka goba IVD ye nngwe le ye nngwe ka boyona, e gopola sebopego sa yona le maikemišetšo a tirišo.

12. Setifikeiti sa ngwadišo

Mongwadiši, morago ga ngwadišo ya sedirišwa sa bongaka goba IVD, o swanetše go nea setifikeiti sa ngwadišo ka tsela ye e laeditšwego ka tlase:

MEDICINES AND RELATED SUBSTANCES ACT 1965, (MOLAO 101 WA 1965)

SETIFIKEITI SA NGWADIŠO SA SEDIRIŠWA SA BONGAKA GOBA IVD

Go netefatšwa gore ngwadišo ya sedirišwa sa bongaka goba IVD ye e hlalošitšwego ka tlase e dumeletšwe ke Khansele go ya ka dipeelano tse di laeditšwego.

1. Leina.....
2. Nomoro ya ngwadišo.....
3. Legoro la sedirišwa sa bongaka goba IVD.....
4. Bakeng sa didirišwa tša bongaka tšeo di kopantšwego leina le palo ya selo/dilo tša šetule, goba selo/dilo tša paolotši
5. Khouto ya tsela ya maina.....
6. Dipeelano tša ngwadišo ya sedirišwa sa bongaka goba IVD.....
7. Ngwadišo ka leina la (mong wa setifikeiti sa ngwadišo).....
8. Leina le aterese ya bodulo ya motšweletši wa mathomo.....
9. Letšatšikgwedi la ngwadišo.....

Mongwadiši

Neilwe go la ka la 20

13. Dikarolwana le diripana

- (1) Motho yo a rekišago karolwana ya maikemišetšo a go beabakeng ga karolwana ya go swana goba ye bohlokwa ya go swana goba karolo ya sedirišwa sa bongaka goba IVD, yeo e senyegilego goba ye e feletšwego ke nako, bakeng sa go hlokomela goba go thoma gape mošomo wa sedirišwa sa bongaka goba IVD ntle le go fetoša kudu mošomo wa yona goba polokego ya yona, o swanetše go—
- (a) netefatša gore karolwana ga e ame gampe polokego le tiragatšo ya sedirišwa sa bongaka goba IVD; le
- (b) go tšwelapele ka go nea mabaka a go hlohleletša bohlatse mme ka kgopelo, go phethagaletša bohlatse go Khansele.
- (2) Karolwana ya maikemišetšo a go beabakeng karolwana goba seripana sa sedirišwa sa bongaka goba IVD mme e fetoša tiragatšo kudu goba polokego ya sedirišwa sa bongaka goba IVD e bonwa bjalo ka sedirišwa sa bongaka goba IVD.

14. Tshenyo ya didirišwa tša bongaka goba di-IVD

- (1) Sedirišwa sa bongaka goba IVD ga se ya swanela go lahlwa tseleng ya tshepetšo ya mantle ya masepala.
- (2) Tshenyo goba tahlo ya sedirišwa sa bongaka goba IVD, e swanetše go diragatšwa ka tsela ye e laetšwego ke Khansele.

15. Mokgwa wa go tšea dišupo ge go dirwa nyakišišo, setifikeiti seo se tligelo go newa le pego ya dipoelo phetleko

- (1) Mofetleki aka tšea sešupo goba palo efe goba efe ya dišupo, ya didirišwa tša bongaka goba IVD bakeng sa mohola wa teko, hlahlobo goba phetleko ka motho yo a nago le maswanedi profešeneng ya gagwe, go swana le moetšenere, molokiši goba ngaka ye e nyakišišwago malwetši.
- (2) Sešupo goba dišupo tše di hlalošitšwego go molawana (1) di swanetše go—
- (a) tšewa ge motho yo a lego taolong ya sedirišwa sa bongaka goba IVD a le gona, goba ge motho yoo a se gona, hlatse e le gona;
- (b) tšewa mme di bolokwe ka tsela ya go netefatša botshepegi ka nako ya tshepetšo ya hlahlobo ka moka ya sešupo;

- (c) phuthelwa le go phethagaletša ditlankana ka mo go swanetšego goba go swaya ka tsele yeo e dumeletšwego; le go
 - (d) romelwa ka mokgwa ofe goba ofe wo o swanetšego go motho yo a nago le boithutelo lefelong la gagwe la mošomo go swana le mofetleki, moetšenera wa bongaka, molokiši goba ngaka ye e nyakišišwago malwetši, gammogo le setifikeiti seo se saenilwego ke mofetleki, ngwalollo yeo e swanetšego go newa motho yo a hlalošitšwego go tema (a) ke mofetleki ka bonako bjo bo kgonagalago.
- (3) Motho yo a nago le boithutelo yo a hlalošitšwego go molawana (1), ka bonako bjo bo kgonegago, o swanetše go leka, hlahloba goba fetleka sešupo mme a bege dipelo tša teko, hlahlobo goba phetleko.(1), go ya ka Melawana, a ka tšea sešupo ka nako ya hlahlobo, gotšwa go motšweletši, mophatlalatši, rakgwebokgolo goba morekiši, bakeng sa teko, hlahlobo goba phetleko.
- (5) Go sa setšwe molawana (1), Khansele e ka kgopela mong wa setifikeiti sa ngwadišo gore a nee Khansele sešupo sa sedirišwa sa bongaka goba IVD bakeng sa go leka, hlahlobo goba go fetleka sešupo.
- (6) Setifikeiti seo se newago go ya ka molawana wo goba pego yeo e hlalošitšwego go molawana (3), se swanetše go romelwa go Mongwadiši mo matšatšing a 7 go thoma ka letšatšikgwedi la kabo.

16. Maitshwara a teko ya bongaka le dinyakišišo tša bongaka

- (1) Motho yo a nyakago go thoma goba go dira—
- (a) nyakišišo ya bongaka malebana le sedirišwa sa bongaka seo se sa ngwadišwago;
 - (b) phetleko ya bongaka ya tiragatšo ya IVD; goba
 - (c) maikemišetšo a mohola wo mofsa a sedirišwa sa bongaka se se ngwadišitšwego goba goba IVD, o swanetše go dira kgopelo go Khansele foromong yeo e laeditšwego ke Khansele, bakeng sa tetla ya go dira teko ya bongaka, nyakišišo goba hlahlobo ya tiragatšo.
- (2) Kgopelo ye e hlalošitšwego go molawana (1) e swanetše go sepela le tefelo yeo e beilwego gape e swanetše go sepela le tshedimošo ye e latelago:
- (a) Leano la nyakišišo ya bongaka goba teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa tshepetšo ya IVD;
 - (b) pukwana ya monyakišišo yeo e nago le, mo go swanetšego, tshedimošo ye malebana ya peleng ya bongaka, bomekgeniki, elektroniki le ya radiešene mme mo go

- swanetšego, tshedimošo ya bongaka ya motho goba phoofolo le sedirišwa sa bongaka goba IVD ye malebana;
- (c) Puku ya boitsebišo ya monyakišiši;
 - (d) pego ya mosaeno ka mokgopedi le monyakišiši ya gore ba tseba, ebile ba kwešiša tshepetšo mme ba tla, tiragatšong ya nyakišišo ya bongaka goba teko ya bongaka, obamela Tiragatšo Gabotse ya Bongaka bjalo ka ge go Khansele e laeditše;
 - (e) ditokomane tša tumelo ka tsebo le dithekgo tša komiti ya maitshwaro a botse yeo amogetšwego ke Khansele; le
 - (f) leina le aterese ya sehlengwa seo teko ya bongaka goba nyakišišo ya bongaka e tlilego go diragatšwa go sona.
- (3) Leano la nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa tshepetšo ya IVD yeo e hlalošitšwego go molawana (2)(a) e swanetše go ba le tshedimošo ye e latelago:
- (a) Nomoro ya batho goba diphoofole tša nyakišišo, ka mo go hlokegago, tšeo di tlilego go amega nyakišišong ya bongaka, tekong ya bongaka goba phetlekong ya tiragatšo ya bongaka bakeng sa IVD;
 - (b) leina la monyakišiši yo a swanetšego go ba-
 - (i) motho yo a nago le boithutelo bjo malebana yo a dumeletšwego ke Khansele;
 - (ii) motho yo a dulago mo Rephabliki; gape
 - (iii) yo a lego taolong ya mafelo ao diteko tša bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD e diragatšwago go ona;
 - (c) palo ya dikarolwana tša sedirišwa sa bongaka sa dinyakišišo goba IVD yeo e tlilego go dirišwa tekong ya bongaka, nyakišišong ya bongaka goba phetlekong ya tiragatšo ya bongaka ya IVD;
 - (d) tshedimošo malebana le sebopego, tšweletšo le tiragatšo ye e letetšwego ya sedirišwa sa bongaka goba IVD; le
 - (e) tshedimošo efe goba efe yeo e laetšwago ke Khansele.
- (4) Nyakišišo ya bongaka le teko ya bongaka goba phetleko ya tiragatšo ya bongaka ya IVD e swanetše go diragatšwa go ya ka methalohlahli ya tiragatšo ya bongaka ye e swanetšego yeo e laolwago ke Khansele.

- (5) Motho ga se a swanela go diragatša nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD yeo e hlalošitšwego go molawana (1), ntle le tetla ya Khansele.
- (6) Motho yo a dirago nyakišišo ya bongaka goba teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD o swanetše go romela go Khansele-
- (a) dipego tša tshepetšo morago ga dikgwedi tše dingwe le tše dingwe tše tshela go thoma ka letšatšikgwedi la nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa phetleko ya tiragatšo ya IVD ye e thomilwego, mme morago ga matšatšikgwedi a 30 morago ga phethagaletšo goba phedišo nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD; le
- (b) dipego tša tiragalo ye kahlanong semeetseng goba ka bonako bjo bo kgonegago.
- (7) Khansele e ka-
- (a) kgopela tshedimošo ye nngwe;
- (b) fetleka nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD; goba
- (c) emiša tetla ya go dira nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD, ge Khansele e na le boikgopolelo bja gore-
- (i) polokego ya baamegi ba nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD ga se ya netefatšwa; goba
- (ii) gore mabaka a saense a go diragatša nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD, a fetogile.
- (8) (a) Tshedimošo ye e latelago ya sedirišwa sa bongaka goba IVD yeo e hlalošitšwego go molawana (1) e swanetše go phethagaletšwa, mo go hlokegago:
- (i) Maikemišetšo a mohola goba tirišo ya sedirišwa sa bongaka nyakišišong ye e šišintšwego ya bongaka goba tekong ya bongaka;
- (ii) batho le ditaetšo tšeo maikemišetšo a sedirišwa sa bongaka a lebišitšwego;
- (iii) leina goba nomoro ya sebopego goba mohuta, go akaretšwa mohuta wa mananeotirišo a khophuthata le dilomaganyo, ge di le gona, bakeng sa go dumelela boitsebišo ka botlalo;
- (iv) hlalošo ya gore khwetšagalo e tla phethagaletšwa ka tsela efe ka nako ya le morago ga nyakišišo ya bongaka, (e.g. ka kabelo ya nomoro ya sehlopha, nomoro ya karolo goba palotatlano);

- (b) Sedirišwa sa bongaka goba IVD e swanetše—
- (i) mo go kgonegago, go direlwa setlankana sa leina le aterese ya lefelo leo nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD e tšilego go phethagaletšwa; le
- (ii) go direlwa setlankana sa gore "bakeng sa tirišo ya nyakišišo fela".
- (9) Khansele e ka, go ya ka dipeelano tšeo di ka laetšwago ke Khansele, dumelela tiragatšo ya nyakišišo ya bongaka, teko ya bongaka goba phetleko ya tiragatšo ya bongaka bakeng sa IVD.

17. Pego ya tiragalo ye kgahlanong le hlokomelo bakeng sa didirišwa tša bongaka le di-IVD

- (1) Moemedi yo a dumeletšwego goba mong wa setifikeiti sa ngwadišo malebana le sedirišwa sa bongaka goba IVD o swanetše go tsebiša Khansele, ka mkgwa woo ebile ka nako yeo e laolwago ke Khansele, ka tiragalo ye e lebeletšwego ye kgahlanong, yeo e begilwego go yena, e direga ka lebaka la tirišo ya sedirišwa sa bongaka goba IVD.
- (2) Moemedi yo a dumeletšwego goba mong wa setifikeiti sa ngwadišo seo se hlalošitšwego go molawana (1) o swanetše -
- (a) mo nakong ye e beilwego ke Khansele, morago ga khwetšo ya pegu ye e hlalošitšwego go molawana (1), go tsebiša Khansele ka ga magato ao a swanetšo go phethagaletšwa bakeng sa go šomana le tiragalo ye kgahlanong;
- (b) ge a kgopelwa ke Khansele, go dira phetleko ye kopana ya polokego le tiragatšo ya sedirišwa sa bongaka goba IVD mme a romele dipelo tša gona go Khansele mo nakong ye e laeditšwego; gape
- (c) morago ga khwetšo ya dipelo tše diu hlalošitšwego go tema (b), moo Khansele e laetšago gore sedirišwa sa bongaka goba IVD e ka ba ya tirišo ye e sa bolokegago, romela go Khansele, ge go na le hlokego-
- (i) dipego tša tiragalo ye kgahlanong ya sedirišwa sa bongaka se se emišitšwego malebana le sedirišwa sa bongaka goba IVD;
- (ii) mo go swanetšego, sedirišwa sa bongaka goba dipalo tša tirišo tša IVD, dipego tša polokego tša nako le nako le dinyakišišo ya tiragatšo; le
- (iii) tshedimošo efe goba efe yeo e hlokwago ke Khansele.

- (d) Iota le go hlokomela goba go ba le phihlelelo ya direkhoto tša tshedimošo ya tiragalo ye kahlanong malebana le didirišwa tša bongaka goba di-IVD tša gagwe goba tša yona.
- (3) Ga go selo mo molawaneng wo, seo se ka hlathollwago bjalo ka se se thibelago motho go bega tiragalo ye kahlanong go Khansele.
- (4) Ntle le molawana (1) goba (3), modiriši yo a tsebago ka ga tiragalo ye kahlanong yeo e hlotšwego gona e belaelwago gore e hlotšwe ke sedirišwa sa bongaka goba IVD ka nako ya tirišo ya goba diragatšo ya nyakišišo ya morago ga theko, o swanetše go bega tiragalo go mong wa laesense, mong wa setifikeiti sa ngwadišo, motšweletši, moemedi yo a dumeletšwego goba Khansele.

18. Nyakišišo

- (1) Khansele e ka diragatša nyakišišo malebana le sedirišwa sa bongaka goba IVD, motšweletši wa sona, mophatlalatši goba rakgwebokgolo ge-
 - (a) sedirišwa sa bongaka goba emišitšwe mo Afrika Borwa goba nageng efe goba efe;
 - (b) tiragalo ye kahlanong ya sedirišwa sa bongaka goba IVD e begilwe mo Afrika Borwa goba nageng efe goba efe;
 - (c) sedirišwa sa bongaka goba IVD e belaelwa goba go hweditšwe gore ga e obamele dinyakwa tša Molao;
 - (d) go na le temošo ya boditšhabatšhaba malebana le sedirišwa sa bongaka, IVD goba motšweletši wa sedirišwa sa bongaka goba IVD; goba
 - (e) bakeng sa mabaka afe goba afe, Khansele e bona hlokego ya go dira nyakišišo ka ga sedirišwa sa bongaka goba IVD.

19. Melato le dikotlo

- (1) Motho yo a palelwago go obamela, yo a tshelago ditaelo tša, gona yo a phethagaletšago tshedimošo ya bofora ka maikemišetšo malebana le -
 - (a) melawana 3 goba 4 malebana le ditšwantle goba thomelo ya didirišwa tša bongaka goba di-IVD;
 - (b) melawana 5 malebana le laesense ya tšweletšo, go dira bjalo ka mophatlalatši goba go dira bjalo ka rakgwebokgolo wa didirišwa tša bongaka goba di-IVD;

- (c) melawana 14 malebana le tshenyo ya didirišwa tša bongaka goba di-IVD;
 - (d) melawana 16 malebana le maitshwaro ditekong tša bongaka;
 - (e) melawana 21 malebana le dipapatšo tša didirišwa tša bongaka goba di-IVD;
 - (f) melawana 22 malebana le ditlankana tša didirišwa tša bongaka goba di-IVD;
 - (g) melawana 23 malebana le ditaetšo tša tirišo ya sedirišwa sa bongaka;
 - (h) melawana 24 malebana le ditaetšo tša tirišo ya IVD;
 - (i) melawana 20 malebana le kobamelo ya Melao ye Bohlokwa yeo e netefaditšwego pegong ya kobamelo; goba
 - (j) melawana 17 malebana le pego ya ditiragalo tše kgahlanong le hlokomelo,
o na le molato mme ka tšhotšhiso a ka hwetša faene, goba a išwa kgolegong botelele bja nako ye e sa fetego mengwaga ye 10.
- (2) Motho yo a rekišago sedirišwa sa bongaka goba IVD yeo e feletšwego ke nako o na le molato mme ge a tšhotšhiswa o tla lefela faene, goba go išwa kgolegong botelele bja nako ye e sa fetego mengwaga ye 10.

20. Kobamelo ya dinyakwa

- (1) Sedirišwa sa bongaka goba IVD e swanetše go sepelelana le maemo le ditaetšo tšeo dirometšwego go Khansale foromong yeo e hlalošitšwego go molawana 8 gape tšeo di dumeletšwego ke Khansale malebana le sedirišwa sa bongaka goba IVD.
- (2) Sedirišwa sa bongaka goba IVD e swanetše go sepelelana le Melao ye Bohlaokwa ye e rometšwego go Khansale ka pego ya kobamelo yeo e hlalošitšwego go molawana 8(7).
- (3) Phapogo ye e šišintšwego go maemo ao a amogetšwego le ditaetšo tše hlalošitšwego go molawana (1) le (2), e swanetše go romelwa go Khansale bakeng sa tetla.

21. Papatšo ya didirišwa tša bongaka goba di-IVD

- (1) Dinyakwa tše dilatelago di šoma papatšong ya sedirišwa sa bongaka goba IVD:
- (a) Didirišwa tša bongaka le di-IVD tša legoro la A le B di ka bapatšwa setšhabeng goba go motho yo a sa rutegago.
 - (b) ntle le molawana (a), dikgotlopo tša banna le basadi di ka bapatšwa setšhabeng.

- (c) papatšo ya sedirišwa sa bongaka goba IVD ga se ya swanela go ba le setatamente seo se fapogilego go, seo se thulanago le, bohlatse bjo bo rometšwego kgopelong bakeng sa ngwadišo ya sedirišwa sa bongaka goba IVD malebana le polokego, boleng, goba phethagaletšo moo bohlatse bo-
 - (i) amogetšwego ke Khansele malebana le sedirišwa sa bongaka goba IVD; gape
 - (ii) bo tsentšwego ditaetšong tše di dumeletšwego bakeng sa tirišo ya sedirišwa sa bongaka goba IVD.
- (d) papatšo ya tsela ya lengwalo ya sedirišwa sa bongaka goba IVD e swanetše go ba le-
 - (i) leina la sedirišwa sa bongaka goba IVD; gape
 - (ii) bakeng sa sedirišwa sa bongaka seo se ngwadišitšwego goba IVD, nomoro ya ngwadišo yeo e neilwego sedirišwa sa bongaka goba IVD;
- (e) (i) ge sedirišwa sa bongaka sa Legoro C goba Legoro D goba IVD e bapatšwa la mathomo go motho yo e ka bago modiriši, tshedimošo ye e ngwadilwego, yeo e swanetšego go ba le tshedimošo yeo e hlalošitšwego go molawana 23 goba molawana 24 ka moo go lego ka gona, e swanetše go newa motho yoo papatšo ya molomo, elektroniki goba ya kgatišo e lebišitšwego go yena; gape
 - (ii) ge sedirišwa sa bongaka goba IVD e bapatšwa ka dinako tša tatellano, tshedimošo e swanetše go hwetšagala ge e kgopelwa.

22. Phethagaletšo ya setlankana sa sedirišwa sa bongaka goba IVD

- (1) Setlankana sa sedirišwa sa bongaka se sengwe le se sengwe goba IVD se swanetše go ba le dintlha tše di latelago:
 - (a) leina le leina la kgwebo ya sedirišwa sa bongaka goba;
 - (b) hlalošo ya setšweletšwa le maikemišetšo a tirišo;
 - (c) khoutu ya lenaneo la setšweletšwa, mo go swanetšego;
 - (d) leina le aterese ya kgwebo ya motšweletš;
 - (e) leina le aterese ya kgwebo ya mong wa setifikeiti sa ngwadišo;
 - (f) mo go swanetšego, taetšo ya gore sedirišwa sa bongaka se na le goba se akaretša selo sa šetule goba sa paolotši;
 - (g) nomoro ya karolo, mo go swanetšego;

- (h) palotatellano, mo go swanetšego;
- (i) bakeng sa dilomaganyo, palotatellano e ka tlošwa go lokelwe nomoro ya taolo mme bakeng sa mananeotirišo a khomphuthara go ka lokelwa nomoro ya mohuta;
- (j) letšatšikgwedi la phelelo ke nako, mo go swanetšego;
- (k) ge letšatšikgwedi la mafelelo le se gona, letšatšikgwedi la tšweletšo;
- (l) taetšo ya dipeelano tša lefelo polokelo le le kgethegilego goba swaro ye e kgethegilego;
- (m) ge sedirišwa sa bongaka se neilwe se hlwekile, taetšo ya seemo sa hlweko mme, mo go swanetšego, mokgwa wa hlwekišo;
- (n) mo go swanetšego, taetšo ya palo ya dikagare tšeo di šaletšego, ye e laetšwago go ya ka boima goba modumo, palo ya dinomoro, goba kopanyo efe goba efe ya mabaka a a laetšago dikagare tša sephuthelwana;
- (o) ditemošo le tšhireletšo, mo go swanetšego; le
- (p) mo go swanetšego taetšo ya gore sedirišwa sa bongaka ke sa maikemišetšo a-
 - (i) tirišo ka o tee;
 - (ii) nyakišišo ya bongaka goba nyakišišo ya tiragatšo ya bongaka pele se rekišwa;
 - (iii) nyakišišo yeo e sego ya bongaka, meholo ya thuto le teko;
 - (iv) meholo ya dipego goba ditaetšo;
 - (v) tirišo ya phekolo ka *in vitro* goba Diteko tšeo di Diretšwego Laboratoring; le
 - (vi) mo go swanetšego, 'bakeng sa tirišo profeshene fela' goba "teko ye kgauswi ya balwetši".
- (2) Setlankana sa sedirišwa sa bonyaka se sengwe le se sengwe goba IVD e swanetše go ngwalwa ka seisimane mme e tšweletšwe-
 - (a) go sedirišwa sa bongaka goba IVD ka boyona; goba
 - (b) sephuthelwaneng sa yuniti ye nngwe le ye nngwe; le
 - (c) sephuthelwanego sa didirišwa tše mmalwa tša bongaka goba di-IVD.

- (3) Ge sedirišwa sa bongaka e le sedirišwa sa bongaka seo se sepeditšwego gape, setlankana se swanetše go laetša leina la modira tshepetšo le boitšhupo ba sedirišwa sa bongaka bjalo ka sedirišwa sa bongaka seo se sepeditšwego gape.
- (4) Ge sephuthelwana sa IVD se akaretša dilo le diathekele tšeo di ka hwetšagalago bjalo ka didirišwa tša bongaka tša IVD tše di sepelago ka botšona, di ka obamela dinyakwa tše di tšweleditšwego go molawana (1).

23. Ditaetšo tša tirišo ya sedirišwa sa bongaka

- (1) Ditaetšo tša tirišo di ka swara tshedimošo ye e latelago ka seisimane:
- (a) leina goba leina la kgwebo la sedirišwa sa bongaka;
 - (b) leina le aterese ya kgwebo ya motšweletši;
 - (c) mo go kgonegago, maikemišetšo a mohola a a dumeletšwego goba tirišo ya sedirišwa sa bongaka mme mo go swanetšego, modiriši yo a tielego go se diriša;
 - (d) dikotsi ye e šaletšego, seemo se kgahlanong le ditlamorago dife goba dife, go akaretšwa tshedimošo yeo e swanetšego go tšweletšwa go molwetši malebana le se;
 - (e) ditaetšo tšeo modiriši a dihlokago bakeng sa go diriša didirišwa tša bongaka ka tshwanelo (mohlala, ge sedirišwa se na le mokgwa wa tekanyetšo, bogolo bja nepagalo bjo bo hlokegago bakeng sa sona);
 - (f) ge sedirišwa sa bongaka se na le , goba se akaretša selo sa šetule goba selo sa paolotši, tsopolo ya selo, ka mo go swanetšego;
 - (g) dintlha tša hlokomelo efe goba efe ya peakanyetšo goba swaro ya sedirišwa sa bongaka pele se dirišwa (mohlala. hlwekišo, kopanyo ya mafelelo, tokišo, bjalobjalo);
 - (h) dinyakwa dife goba dife tša didirišwa tše kgethegilego, goba katišo ye kgethegilego, goba boithutelo bjo bo rilego ba modiriši goba moamegi wa sedirišwa sa bongaka;
 - (i) tshedimošo ye e hlokegago bakeng sa go netefatša gore naa sedirišwa sa bongaka se tsentšwe ka tshwanelo le gore se ka thoma go diragatša ka polokego mme le ka moo motšweletši a ikemišeditšego, gammogo le, moo go swanetšego-
 - (i) dintlha tša seemo, le boipoeletšo, hlokomelo ya thibelo le ya nako le nako gape le hlwekišo goba go tlošotwatsi efe goba efe ya peakanyetšo;
 - (ii) tsopolo ya dikarolwana tše di lahlegago mme le mokgwa wa peobakeng ya tšona;

- (iii) tshedimošo ya tokišo efe goba efe ye e hlokegago go netefatša gore sedirišwa sa bongaka se šoma gabotse mme ya polokego ka nako ya sona ya go šoma; mme
- (iv) mekgwa ya go fediša dikotsi tšeo di lebanego batho bao ba amegago tsenyong, tokišong le hlokomelong ya didirišwa tša bongaka;
- (j) taetšo ya senamelwa sefe goba sefe se se kgethegilego, poloko goba dipeelano tša swaro tšeo di šomago;
- (k) ge sedirišwa sa bongaka se rometšwe se hlwekile, ditaetšo bakeng sa ge sephuthelwana sa hlweko se ka senyega pele se dirišwa;
- (l) ge sedirišwa sa bongaka se rometšwe se sa hlweka, ka maikemišetšo a gore se hlwekišwe pele se dirišwa, ditaetšo tše swanetšego tša hlwekišo;
- (m) ge sedirišwa sa bongaka e le seo se ka šomišwago gape, tshedimošo ya tshepetšo ye e swanetšego ya tetla ya tšhomišo gape, go akaretšwa hlwekišo, tlošotwatsi, phuthelo, le, mo go swanetšego, mokgwa wa hlwekišo gape go akaretšwa tshedimošo ya go tsopola ge sedirišwa sa bongaka se sa swanela ke tirišo gape (mohlala, maswao a tshenyego ye e tseneletšego goba palo ya taetšo ya tirišo ye e dumeletšwego);
- (n) didirišwa tša bongaka tšeo e lego tša tirišo gammogo le didirišwa tša bongaka goba tša mohola kakaretšo-
 - (i) tshedimošo ya go tsopola didirišwa tša bongaka goba didirišwa, bakeng sa go hwetša kopanyo ye bolokesegilego; le
 - (ii) tshedimošo ya mathata afe goba afe ao a tsebjago dikopanyong tša didirišwa tša bongaka le didirišwa;
- (o) ge sedirišwa sa bongaka se ntšha radiešene ye kotsi, goba ye e ka bago ye kotsi bakeng sa meholo ya bongaka-
 - (i) tshedimošo ka botlalo ya mokgwa, mohuta, gape mo go swanetšego, bogolo le phatlalatšo ya radiešene yeo ye ntšhitšwego; le
 - (ii) mokgwa wa go šireletša molwetši, modiriši, goba moamegi yo mongwe go radiešene ye e sego ya maikemišetšo ka nako ya tirišo ya sedirišwa sa bongaka;
- (p) tshedimošo ye e kgontšhago modiriši le molwetši go tsebišwa ka ditemošo, ditšhireletšo, magato ao a tilego go tšewa le mellwane ya tirišo malebana le

sedirišwa sa bongaka tšeo di swanetšego go phethagaletšwa ke tshedimošo, mo go swanetšego-

- (i) ditemošo, ditšhireletšo le magato ao a swanetšego go tsewa bakeng sa tšhomompe ya sedirišwa sa bongaka goba diphetogo phethagaletšong ya tšona tšeo di ka amago polokego;
 - (ii) ditemošo, ditšhireletšo le magato ao a swanetšego go tsewa malebana le tlhagišo go dikhetšo tša ka ntle tše di bonagalago goba maemo a tikologo, go swana le mafelo a makenethiki, ditlamorago tša ka ntle tša elektroniki le ditšweletšo tša elektromeknethiki, radiešene ye malebana le ditshepetšo tša phekolo le theraphi, kgatelelelo, bonola goba thempheretšha;
 - (iii) ditemošo, tšhireletšo le magato a a tšerwego malebana le dikotsi tša tsenelelo tšeo di hloiwago ke khwetšagalo yeo e bonetšwegopele ya sedišwa sa bongaka ka nako ya nyakišišo ya phetleko, hlokomelo ya theraphi goba tirišo (mohlala, tsenelelo ya elektromeknethiki yeo e ntšhwago ke sedirišwa sa bongaka yeo e amago sedirišwa se sengwe);
 - (iv) ge sedirišwa sa bongaka se sepetša selo sa šetule goba selo sa paolotši, mellwane efe goba efe goba go se sepelelane kgethong ya selo se se tšilego go romelwa;
 - (v) temošo, tšhireletšo le mellwane ye malebana le selo sa šetule goba selo sa paolotši se se tsentšwego sedirišweng sa bongaka bjalo ka karolwana ye bohlokwa ya sedirišwa sa bongaka; le
 - (vi) ditemošo tše malebana le matheriale yo o tsentšwego sedirišweng sa bongaka tšeo di hloiwago kankere, phetošo goba kotsi goba tšeo di ka bakago temošo goba aletši go molwetši goba modiriši;
- (q) ditemošo le ditšhireletšo tše swanetšego go diragatšwa tše malebana le tahlo ya sedirišwa sa bongaka, dilomaganyo tša sona le didirišwa tše di dirišwago le sona, mo go swanetšego. Tshedimošo ye e swanetše go akaretša, mo go swanetšego-
- (i) dikotsi tša phetelo goba maekrobale (mohlala, ditlošo, dinalete goba didirišwa tša puo tše di tšhilafaditšwego ke dilo tšeo e ka bago tša phetelo tšeo di tšwago bathong);
 - (ii) dikotsi tša tikologong (mohlala, dipeteri goba matheriale wo o ntšhago radiešene ya maemo a kgonagalo ya go hlola kotsi); le
 - (iii) dikotsi tše di bonagalago (mohlala, magare);

- (r) bakeng sa didirišwa tša bongaka tšeo e lego tša go dirišwa ke motho yo a sa rutegago, mabaka ao modiriši a swanetšego go bolela le mošomi wa tša maphele ka ona;
 - (s) letšatšikgwedi la kabo goba mohuta wa maefelelo wa ditaleo tša tirišo gape, mo go kgonegago, nomoro ya tsopolo; le
 - (t) ditaleo tše swanetšego tša tirelo le hlokomelo bakeng sa didirišwa tša sethekgeniki le didirišwa tša bongaka, mo go swanetšego.
- (2) Ditalo tša tirišo ya sedirišwa sa bongaka di swanetše go akaretšwa ka thekišo ya sedirišwa sa bongaka se se ngwe le se se ngwe, efela, ditaleo tša tirišo ya didirišwa tša bongaka tša Legoro la A di swanetše go akaretšwa mo go hlokegago.

24. Taetšo ya tirišo ya IVD

- (1) Ditaetšo tša tirišo di swanetše go ba le tshedimošo ye e latelago ka Seisimane:
- (a) leina goba leina la kgwebo;
 - (b) leina le aterese ya motšweletši;
 - (c) maikemišetšo a mohola le tirišo go akaretšwa efela go sa felele go-
 - (i) seo se bonwago;
 - (ii) mošomo wa sona;
 - (iii) bolwetši bjo bo itšego, seemo goba ntiha ya kotsi ya kgahlegelo yeo e swanetšego go hwetšwa, hlalošwa goba go farologanywa;
 - (iv) gore ke boitiragaletšo goba aowa;
 - (v) gore ke ya boleng goba tša dipalo;
 - (vi) mohuta wa ditšhupetšo tšeo di hlokegago (mohlala, seramo, polasma, maadi, payopsi ya tlhalenama, moroto); le
 - (vii) batho ba teko;
 - (d) taetšo ya gore ke ya tirišo ya phekolo ka *in vitro* gape, mo go swanetšego, bakeng sa "tirišo ya profešene fela", bakeng sa "teko pele ga molwetši", bakeng sa "lefelo la hlokomelo", bakeng sa "go iteka ka bowena" goba bakeng sa "tirišo ya nyakišišo fela"
 - (e) modiriši yo e diritšwego yena, ka mo go swanetšego;

- (f) molao wa teko;
- (g) hlalošo ya selo, ditokišo le ditaelo le mellwane efe goba efe ge didirišwa (mohlala, di swanetše sedirišwa sa maikemišetšo fela);
- Gopola: diphuthelwana tša IVD di akareša dilo tše di sepelago ka botšona le diathekele tše di ka hwetšagalago bjalo ka di-IVD tše sepelago ka botšona. Seemong se, mo go swanetšego, di-IVD tše di swanetše go obamela ditaelo tša tirišo tše di lego karolong ye;
- (h) hlamego ya setšweletšwa ka hlago le hlamego ya didirišwa tše di šomago tša dilo goba diphuthelwana gammogo le setatamente, mo go swanetšego, gore sedirišwa sa bongaka se na le didirišwa tše dingwe tše di ka huetšago tekanyetšo;
- (i) lenaneo la matheriale yeo e neilwego le lenaneo la matheriale ye e kgethegilego ye e hlokegago efela e sa phethagaletšwa;
- j) bakeng sa di-IVD tirišo ya maikemišo gammogo le di-IVD tše dingwe goba didirišwa tša bongaka, goba didirišwa tša mohola kakaretšo-
- (i) tshedimošo ya go tsopola didirišwa tše tša bongaka goba didirišwa, bakeng sa go hwetša kopanyo ye e bolokegilego; le
- (ii) tshedimošo ya mellwane yeo e tsebjago go dikopanyo tša didirišwa tša bongaka le didirišwa;
- (k) taetšo ya dipeelano dife goba dife tša poloko ye e kgethegilego le swaro tše di šomago;
- (l) phethagaletšo tirišong ye e ka akretšago, dipeelano tša poloko, botelele bja nako ya poloko morago ga pulo ya mathomo ya seswari sa mathomo, gammogo le dipeelano tša poloko le swanelo ya ditharollo tša mošomo, mo go swanetšego;
- (m) ge IVD e phethagaletšwe e hlwekile, ditaelo bakeng sa tshenyego ya phuthelo ye hlwekilego pele ga tirišo;
- (n) tshedimošo ye e dumelelago modiriši go tsebišwa ka ditemošo, ditšhireletšo, magato ao a swanetšego go tšewa le mellwane ya tirišo malebana le IVD, yeo e swanetšego go phethagaletša ke tshedimošo, mo go swanetšego-
- (i) ditemošo, ditšhireletšo le magato ao a swanetšego go tšewa bakeng sa tshenyego ya IVD goba tshenyego ya yona yeo e laetšago ke diphetogo tša ponagalo tše di ka amago tiragatšo;
- (ii) ditemošo, ditšhireletšo le magato ao a swanetšego go tšewa malebana le tšweletšo dikhetšong tše di nago ke kgonego ya ponelopele goba

dipeelano tša tikologo, go swana le mafelo a makenethiki, ditšweletšo tša elektrosthethiki, radiešene ye e sepelelanago le ditshepetšo tša phekolo le theraphi, kgatelelo, bonola, goba thempheretšha;

- (iii) ditemošo, ditšhireletšo le magato ao a swanetšego go tšewa malebana le dikotsi tša tsenelelo tšeo di tšweletšwago ke ponelopele ya go ba gona ga sedirišwa sa bongaka ka nako ya nyakišišo ye itšego ya phekolo, diphetleko, hlokomelo ya theraphi go akaretšwa tsenelelo ya elektromeknethiki yeo e ntšhwago ke sedirišwa sa bongaka yeo e amago didirišwa tše dingwe, mo go swanetšego; le
- (iv) ditšhireletšo tše malebana le matheriale ye tsentšwego go IVD yeo e lego ya go hlola kankere, phetogo goba kotsi goba yeo e ka hlolago temošo le aletši;
- (o) ditemošo le ditšhireletšo tše malebana le matheriale wo o ka hlolago phetelo wo o akareditšwego go IVD;
- (p) mo go kgonegago, dinyakwa tša didirišwa tše kgethegilego go akaretšwa lefelo la phapoši ye hlwekilego, polokego ya radiešene goba boithutelo bjo itšego ba modiriši wa sedirišwa sa bongaka;
- (q) dipeelano tša kgoboketšo, swaro le peakanyetšo ya dišupo;
- (r) dintlha tša peakanyetšo ya hlokomelo efe goba efe goba swaro ya IVD pele e lokela tirišo go akaretšwa kagoleswa le tokišo mo go swanetšego;
- (s) tshedimošo ye e hlokegago bakeng sa go netefatša gore naa IVD e tsentšwe gabotse mme e loketše go dira ka polokego le ka maikemišetšo a motšweletši, gammogo le, mo go hlokegago-
 - (i) dintlha tša seemo, boipoletšo, hlokomelo ya thibelo le ya nako le nako go akaretšwa hlwekišo le tlošotwatši;
 - (ii) tsopolo ya dikarolwana dife goba dife tša didirišwa le gore di bewabakeng ka tsela efe;
 - (iii) tshedimošo ya tokišo efe goba efe ye e hlokegago go netefatša gore IVD e šoma gabotse le ka polokego ka nako ya yona ya go šoma; le
 - (iv) mekgwa ya go fokotša dikotsi tšeo di lebanego batho bao ba tsenyago, lokišago goba hlokomelago IVD;
- (t) mo go swanetšego, dieletšo bakeng sa ditshepetšo tša taolo ya boleng;

- (u) mohlala wa tša metrolotši wo o neilwego dilokiši le matheriale ya taolo ya nepagalo, go akaretšwa tsopolo ya matheriale ya tšhupetšo ye e šomago le ditsela tša tekanyetšo ya tšhupetšo tša tatellano ya godimo;
- (v) hlahloba tshepetšo go akaretšwa dipalo le tihathollo ya dipelo mme mo go swanetšego, gore teko ya netefatšo e eleletšwe;
- (w) dibopego tša phetleko ya tiragatšo go swana le boitemošo, taetšo, le nepagalo;
- (x) mo go swanetšego, dibopego tša tiragatšo ya bongaka, go swana le ditemoši tša pheko le taetšo ya pheko;
- (y) mo go swanetšego, dinako tša tšhupetšo;
- (z) tshedimošo ya dilo tše di tsenelelago goba mellwane ya go swana le bohlatse bja ponagalo, haephaletimia goba haemolesese, ngwaga wa sešupo wo o ka amago tiragatšo ya sešupo;
- (aa) ditemošo goba ditšhireletšo tše di swanetšego go diragatšwa mabapi le tahlo ya sedirišwa sa bongaka, dilomaganyo tša sona, le didirišwa tše di dirišwago le sona, ge di le gona, tshedimošo e swanetše go e swanetše go akaretša, mo go swanetšego--
 - (i) phetelo goba dikotsi tša maekrobaele;
 - (ii) dikotsi tša tikologo; le
 - (iii) dikotsi tša ponagalo;
- (bb) bakeng sa IVD ya maikemišetšo a tirišo ya motho yo a sa rutegago, mabaka ao modiriši a swanetšego go ikgokaganya le mošomedi wa tša maphelo;
- (cc) mo go swanetšego, bibliokerafi;
- (dd) letšatšikgwedi la phethagaletšo goba phetošo ya bjale ya ditaelo tša tirišo mme, mo go swanetšego, nomoro ya tšhupetšo; le
- (ee) ditaelo tše malebana tša hlokomelo ya metšhene ya sethekgeniki ya IVD, mo go swanetšego.
- (2) ditaelo tša tirišo ya IVD di swanetše go akaretšwa le thekišo ya IVD ye nngwe le ye nngwe, efela, ditaelo tša tirišo ya di-IVD tša Legoro A di swanetše go akaretšwa, mo go swanetšego.

25. Didirišwa tša bongaka tše di dirilwego ka kgethego

Sedirišwa sa bongaka seo se dirilwego ka kgethego se swanetše go tšweletšwa le go rekišwa ka kobamelo ya methalohlahli ye e šomago didirišweng tša bongaka.

26. Rekhotō ya didirišwa tša bongaka tše di tsenyegago le didirišwa tša bongaka tše di dirilego ka kgethego

- (1) rekhotō ya go ya go ile mabapi le sedirišwa sa bongaka se se tsenyegago sa Legoro D le sedirišwa sa bongaka se se kgethegilego sa kotsi ye godimo e swanetše go lotwa lefelong ke sehlongwa sa hlokomelo ya maphelo goba mošomi wa tša maphelo moo didirišwa tša bongaka di rekišetšwago molwetši, mme e swanetše go swara tshedimošo ye e latelago:
 - (a) leina le khoutu ya setšweletšwa sa sedirišwa sa bongaka;
 - (b) letšatšikgwedi leo kgopelo ya sedirišwa sa bongaka se se tsenyegago goba se se dirilwego ka kgethego e dirilwego ka lona;
 - (c) nomoro ya sebopego, nomoro ya sehlopha, le palotatlano, ge e le gona;
 - (d) leina, aterese le nomoro ya boitsebišo ya molwetši;
 - (e) mo go swanetšego, leina la modiriši le, bakeng sa sedirišwa sa bongaka se se tsenyegago, motho yo a nago le maikarabelo a tsenyo ya sedirišwa sa bongaka;
 - (f) leina le aterese ya hlongo ya tša maphelo;
 - (g) leina la motšweletši wa sedirišwa sa bongaka se se tsenyegago goba se se dirilwego ka kgethego; le
 - (h) tshedimošo ye malebana le sebopego, tšweletšo le tiragatšo ya sedirišwa sa bongaka go akaretšwa tiragatšo ye e letetšwego.
- (2) Rekhotō ya kgopelo e swanetše go swarwa atereseng ya kgwebo ya morekiši botelele bja nako ya mengwaga ye mehlano go feta nako ya tšhomo ye e letetšwego ya sedirišwa sa bongaka.
- (3) Motšweletši, mophatlalatši goba rakgwebokgolo ya Legoro D goba didirišwa tša bongaka tše di tsenyegago ebile tše di dirilwego ka kgethego o swanetše go lota rekhotō ya Legoro D goba didirišwa tša bongaka tše di tsenyegago ebile tše di dirilwego ka kgethego ka mokgwa wa setlakana sa kgopelotefelo-
 - (a) letšatšikgwedi la phetisetšo ya theko ye nngwe le yenngwe;
 - (b) leina la kgwebo la sedirišwa sa bongaka;
 - (c) leina le aterese ya moreki yo mongwe le yo mongwe;

CONTINUES ON PAGE 130 - PART 2



Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID AFRIKA

Vol. 618

9 December 2016
Desember

No. 40480

PART 2 OF 5

N.B. The Government Printing Works will not be held responsible for the quality of "Hard Copies" or "Electronic Files" submitted for publication purposes

ISSN 1682-5843



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

- (d) palo ya tše direkišitšwego; le
 - (e) nomoro ya sehlopha goba palotatellano.
- (4) Rekhotso ye e hlalošitšwego go molawana (3) e swanetše go lotwa botelele bja nako ya mengwaga ye masomehlano go tloga ka letšatšikgwedi la thekišo.

27. Dipeakanyetšo tša nakwana mabapi le motšweletši wa go hloka laesense, motšweletši goba rakgwebokgolo

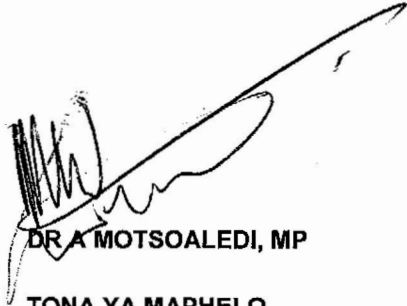
- (1) Motšweletši, mophatlalatši goba rakgwebo yo a, ka nako ya go thoma ga Melawana, rekišago didirišwa tša bongaka goba di-IVD mo Rephabliki, go ya ka molawana 5, o bonwa bjalo ka ya a dirago go ya ka molao.
- (2) Khansale e swanetše go nea tsebišo *Kuranteng ya mmušo* e bitše batšweletši bao go hloka dilaesense, baphatlalatši le borakgwebokgolo, mme tsebišo e swanetše go tšweletša dipeelano le dinako tša go dira laesense, mme le gore, ka nako ya go dira dilaesense, batšweletši, baphatlalatši le borakgwebokgolo ba tla be ba dira go ya ka molao.

28. Dipeakanyetšo tša nakwana malebana le didirišwa tša bongaka tše di sa ngwadišwago le di-IVD

- (1) Sedirišwa se se sa ngwadišwago goba IVD ye e rekišwago mo Rephabliki ka nako ya go thoma go šoma ga Melawana, go ya ka molawana 8, e bonwa bjalo ka ye e rekišwago go ya ka molao go fihlela mafelelong a nako ya tsebišo yeo e hlalošitšwego go molawana (2), bakeng sa tsebišo ya bongaka goba IVD.
- (2) Khansale e swanetše go, ka nako le nako, go nea tsebišo *Kuranteng ya mmušo* e bitša ngwadišo ya didirišwa tša bongaka le di-IVD, mme tsebišo yeo e swanetše-
- (a) go tšweletša gore ke magoro afe a didirišwa tša bongaka ao a swanetšego go ngwadišwa; gape
 - (b) go phethagaletša dipeelano le nako ya go dira kgopelo ya ngwadišo.
- (3) Ntle le molawana (1), Khansale e ka kgopela sedirišwa sa bongaka goba IVD go obamela dinyakwa tše Khansale e ka di laetšago bakeng sa go netefatša gore sedirišwa sa bongaka goba IVD e fihlelela Molao ye Bohlokwa ya polokego le tiragatšo, ye e laolwago ke Khansale.

29. Thaetlele ye kopana

Melawana ye e bitšwa Melawana ye mabapi le Didirišwa tša Bongaka le Didirišwa tša Bongaka tša Phekolo ka/n *Vitro* (di-IVD).



DR A MOTSOALEDI, MP

TONA YA MAPHELO

LETŠATŠIKGWEDI: