21 July 2014

SAMED (The South African Medical Device Industry Association) submission of comments on

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

for the attention of the

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Comments on Draft Regulations as published in Government Gazette 37579

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EXECUTIVE SUMMARY

1. SAMED (The South African Medical Device Industry Association), the representative body of medical device and IVD manufacturers, importers and distributors in the South African market, welcomes the opportunity to comment on the Draft Medical Device Regulations, as published for comment on 22 April 2014.

2. SAMED supports the promulgation of regulations that are appropriate for the South African market, that leverage on international experience and that of recognised jurisdictions, and which ensure speedy market access for devices, the life cycle of which are between 2 to 4 years in many instances.

3. It is noted that the regulations follow the current 2003 General Regulations promulgated for medicines. Although some portions would also be relevant, thematically, for devices, the general international approach to medical device regulations is fundamentally different to that taken in medicines regulation. The main difference is that medical device “evaluations” do not take place in the regulatory authority itself, but are undertaken by external bodies (“conformity assessment bodies” – CABs or “notified bodies”). This arrangement is pragmatic – due to the vast array of devices, it is virtually impossible to employ specialists that would be able to cover all these fields internally. Internationally, only one regulator, the FDA, is doing some form of internal assessment, but employs more than 3000 staff members to do so. Even the FDA recognises some external assessments.

4. Most regulators in middle-income countries such as South Africa adopt systems of recognition of regulatory work, reports and findings undertaken by others – thereby creating (as was included in the 2011-version of the draft Device Regulations) a system of abbreviated reviews prior to registration.

5. Most regulators also adopt the framework created by the International Medical Device Regulators Forum (IMDRF, previously GHTF), to ensure alignment and ease of adoption of work undertaken in recognised jurisdictions. SAMED recommends a complete assessment of the proposed framework, both in regulations and in implementation, against the IMDRF documents, which differ in some respects for medical devices and IVDs.

6. SAMED notes that the Draft Regulations refer to the “Council”, which leads one to the conclusion that the regulations are to be issued under Act 101 of 1965 in its current format (i.e. excluding legislative amendments included in Act 72 of 2008, which are essential, in SAMED’s view). However, on closer inspection it is apparent that references are made to sections in Act 101 of 1965, as amended by Act 72 of 2008. Furthermore, even with Act 72-amendments, not all provisions included in the Draft Regulations are empowered by Act 101 of 1965, as amended by Act 72 of 2008, and SAMED points these out in the submission below.

1 In Vitro Diagnostic Medical Devices.
7. SAMED urges the adoption of a regulatory system that is efficient and effective. To this end, the proposals contained in Bill 6 of 2014 to create an oversight body are to be welcomed. However, this means that, without Bill 6 having been adopted by Parliament, no effective regulatory body, viz. SAHPRA, can be created. SAMED urges the Department and MCC to consider the creation of a medical device and IVD division within SAHPRA, with dedicated human resources, adequately experienced and trained in medical devices and IVDs, as well as a dedicated Medical Devices and IVD Registrar, to ensure the necessary capacity and focus on devices and IVDs. Current reported backlogs in medicines and complementary medicines regulatory measures should not affect the important project of device regulation.

SAMED uses this opportunity to request a joint workshop with the Department and MCC, including the drafters of the regulations. This would afford both industry and the regulators the chance to benefit from best practices in medical device regulation, with a view to successful implementation of a regulatory framework under MCC/SAHPRA. During such a workshop SAMED members are more than willing to share experiences from local companies who are registering their locally manufactured products in markets such as the EU and USA, as well as the experiences of multinationals who register products and are subject to regulations in developed, as well as middle-income and developing markets.

8. The draft regulations would also necessitate changes to-and/or alignment with the Hazardous Substances Act, Act 15 of 1973 (for electromedical and radiation-emitting medical devices and IVDs), as well as changes to the Foodstuffs, Cosmetics and Disinfectants Act, Act 54 of 1972 (for borderline medical devices, accessories and other products).

SAMED has consulted widely with experts in the field of medical device regulation and representatives from industry (both locally and internationally), legal practitioners and other stakeholders, and submits the following comments on the draft “General Regulations relating to Medical Devices and in-vitro Diagnostic Medical Devices (IVDs)” as published in the Government Gazette on 22 April 2014.

SAMED trusts that these comments will be taken into consideration for the final version of the regulations.

SAMED looks forward to constructive engagement with the Department of Health in the future on the matter of appropriate and workable regulations for medical devices and in-vitro diagnostics in South Africa.

Yours faithfully,

Tanya Vogt
Executive Officer
SAMED
21 July 2014
Comments on the Draft Regulations per regulation

Changes are proposed in underlined text to denote additions and strikethrough text to denote deletions. Blue text is for provisions that are *ultra vires* with respect to the empowering Act. The rationale for recommended changes is included in a block.

**DEFINITIONS**

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

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

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

Not used in content of regulations

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

Not used in content of regulations.

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

Not used in content of regulations

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

Not used in content of regulations

"adverse event" in relation to a medical device or IVD means possible faults or failures of the medical device or IVD, difficulties in the use of or an undesirable outcome associated with the use of the medical device or IVD, that can or does result in permanent impairment, injury or death to the professional user or patient user.
‘adverse event’ means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a clinical performance study, whether or not related to the device for performance evaluation;

Deletion of "adverse event" definition and substitution of the definition of "adverse event" from the EU MDD guideline to distinguish it from "serious adverse event ", defined later in these regulations (per SAMED recommendation).

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

Delete 'applicant' is not needed - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be authorised representative or manufacturer.

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

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

Delete as not applicable to medical device or IVDs. As they are managed through risk classification and the conformity assessment route, there is generally no prescription activity with devices or IVDs which may be issued through a purchase order process. Devices are generally not prescribed, as many are available in retailers or healthcare facilities. Depends on the risk classification or requirement of the Competent Authority / regulator as a condition of registration.

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

Delete of "and who has submitted an application for the registration of a medical device or IVD":

Definition must distinguish between authorised representative and applicant*, therefore cannot include both in one term.

An authorised representative is not always the applicant*, which is defined elsewhere.

An "applicant" * is defined as responsible for the submission of an application for the registration. Not necessarily the same as the applicant for medical devices, as many devices may...
be marketed by many different distributors.

Note: In Europe, Brazil and other countries, an Authorised Representative can only be a legal person.

*Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer.

'batch number' or “lot number” means a unique number or combination of numbers or cyphers allocated to a lot or a batch by the manufacturer; “Batch, batch number, lot number, serial number” means a unique number or combination of numbers, cyphers, words, symbols or letters assigned by the manufacturer to uniquely identify the device and any of its variants in relation to a lot, batch, instrument, medical device or IVD

The word “Batch” is used in regulation 28, so has been added to this definition. Medical devices, medical equipment, IVDs and IVD instrumentation may make use of any of the terms added above,. which are referenced in regulation 30

“biological medical device” is a device which incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma (human blood derivative) and which is liable to act upon the body with action ancillary to that of the device, that device shall be assessed and authorised in accordance with these regulations

A definition for content in Reg 30 (1) (f) as per the Medical Device Directive 93/42/EEC (European Union).

“borderline medical device” means a device which, at face value may appear to be a medicine or other product, but which, in its performance, complies with the definition of a medical device;

Borderline cases are considered to be those cases where it is not clear from the outset whether a given product is a medical device, an in vitro diagnostic medical device, an active implantable medical device, medicine or not; or alternatively, borderline cases are those cases where the product falls within the definition of a medical device or medicine or other product, but is excluded from the regulation by their scope. Where a given product does not fall within the definition of medical device or is excluded by the scope of the regulations, national legislation may be applicable.
Added definition for regulation on borderline medical devices, included per SAMED’s recommendation.

Reference:” Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices, European Union, 2013”

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

Not used in content of regulations

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

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

Not used in content of regulations.

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

Additions for clinical investigations, as the study must be designed to discover or verify the safety or clinical performance of a medical device. Delete IVD as it should also be noted that, unlike medical devices in general, IVDs are not used in, or on the body but are used outside of the body. In most cases, there is no patient-interaction at all (i.e. a sample is taken from a patient, and analysed in a laboratory).

Note: Chapter 9 of The National Health Act already provides for regulation under the National Health Research Committee and National Health Research Ethics Council.

"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;

"combination device" means a medical device incorporating as an integral part, a substance which if that substance was used separately, would be can be considered to be a medicine medicinal product. Such combination devices, excluding IVDs, shall be assessed and authorised in accordance with these medical device regulations.
Rewording of combination device to align to the GHTF classification rules guideline, Rule 13. If it means that it is a medical device that contains as an integral part a medicinal substance which if that substance was used separately it would be a medicine in itself. In the combination Device it is liable to act on the human body with action ancillary to that of the medical device. This aligns with the current definition of a Medical Devices as in Act 101 of 1965, as well as in its amended form in Act 72 of 2008.

"conformity assessment" means the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Council, to determine that a medical device is safe and performs as intended by the manufacturer and, conforms to the Essential Principles of Safety and Performance for Medical Devices;

Delete “under requirements established by Council” This concept is an IMDRF-accepted concept with a fixed technical meaning globally, which cannot and should not be changed locally, as it is applied by manufacturers and certified against such known and internationally accepted principles. For local and multinational companies in South Africa, their devices and sites have to be internationally aligned and evaluated by similar criteria, so as to ensure global consistency as a measure of quality.

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

"Conformity Assessment Body” definition moved under “C” for alphabetical order

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

Deleted as this is not a function of Council and there are already established international requirements

“continuous use” in terms of medical devices or IVDs means:

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

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

This term is not in the content of the regulations.
“control number”, - means any distinctive symbols, such as distinctive combination of letters or numbers or both from which the history of the manufacturing, packaging, labelling or distribution of a unit, lot or batch of the product can be determined.

Definition of control number added for interpretation of Regulation 30 (1) i - regarding accessories

"custom made medical device" means any medical device specifically made in accordance with a written prescription or order given by a person authorised for the same by virtue of professional qualifications and in accordance with specific design characteristics and is intended for the sole use of a particular user and excludes mass produced medical devices which only need adaptation to meet the specific requirements of the health professional user; but includes any device that is imported once-off (or manufactured locally) for use by a particular patient as prescribed by a particular physician

Definition accommodates exceptional individual patient needs

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

Delete "as required by Council" a declaration of conformity is an IMDRF-accepted concept with a fixed technical meaning globally, which cannot and should not be changed locally, as it is applied by manufacturers and certified against such known and internationally accepted principles. For local and multinational companies in South Africa, their devices and sites have to internationally aligned and evaluated by similar criteria, so as to ensure global consistency as a measure of quality.

“distributor”: Any person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user This definition includes the possibility that more than one distributor may be involved in the supply chain, and excludes logistics providers, i.e. persons involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor;”

Definition included as it is referred to in the content of the regulations e.g. Regulation 8; GHTF/SG1/N055:2009

"essential principles" set out the internationally aligned requirements relating to the safety and performance characteristics of medical devices and IVDs as approved by Council;
Add "internationally aligned" and delete "approved by Council" as this concept is an IMDRF-accepted concept with a fixed technical meaning globally, which cannot and should not be changed locally, as it is applied by manufacturers and certified against such known and internationally accepted principles. For local and multinational companies in South Africa, their devices and sites have to be internationally aligned and evaluated by similar criteria, so as to ensure global consistency as a measure of quality.

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

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

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

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

Note that there may be many HCR's for the same device as many devices may be marketed by many different distributors.

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

"holder of a licence" means a person in whose name a licence for importation, manufacture, distribution, wholesale, in South Africa, has been granted and who is responsible for and making application for the required permits as determined by the Council in a guideline.

"implantable device" means any device, including those that are partially or wholly absorbed, which is intended to be totally introduced into the human body or, to replace an epithelial surface or the surface of the eye by surgical intervention which is intended to remain in place after the procedure, for for at least 60 minutes at least 30 days.
As per international definition- for example, MEDDEV 2.4/1 Rev 9 2010 Classification of medical devices -Guidance for the European Union ; ISO 13485 § 3.5 and GHTF/SG1/N77:2012

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

“Intended use” is the common terminology for medical devices.

“importer” ; is any natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed”

It is proposed that the following GHTF definition for “importer; referred to in regulation 5 be included.

“instructions for use” is information provided by the manufacturer to inform the device user of the medical device’s intended purpose and proper use and of any precautions to be taken;

It is proposed the following GHTF definition; “Instructions for Use” be included; Refer to regulation 11, 26, 29, 30

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

Not used in content of regulations

“IVD”- a specific type of diagnostic medical device, whether used alone or in combination with other IVDs, 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, compatibility purposes. (This includes reagents, calibrators, control materials, specimen receptacles, and software relating to a specific IVD). This excludes products for general laboratory use which are not IVDs unless, in view of their characteristics, they are used for the purposes outlined in the definition of an IVD. This also excludes IVDs where the intended use is for non-clinical purposes without any medical objective, “RUO - Research use only” IVD Devices, LDTs laboratory developed tests, IVDs for use in demonstrations, teaching or training.

No definition is in the “Act” for in vitro Medical Device (IVD) [but is in Act 72 of 2008]. SAMED proposes the following definition for “IVD” reference GHTF SG1/N071:2012 definition.

IVDs can also be used for non-clinical purposes in other industries other than the examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.
"Medical device- or IVD label" means written, printed or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices, or referenced in an electronic uniform resource locator (url). Label shall be referred to as 'medical device label' in the regulatory document.

**SAMED proposes the addition of a definition for a label; refer regulation 30**

"lay person" means an individual that does not have formal training in a relevant field or discipline relating to the use of a medical device or IVD;

**Adapted definition to limit the term to medical device and IVD field or discipline**

“listing” means the authorisation of the sale of Class A medical devices and Class A and B IVDs by the Authority based on an authorised representative or manufacturer’s submission of information relating to the medical device or IVD intended to be sold in the Republic as per internationally accepted criteria and those used in comparative jurisdictions.

**To make provision for a truncated registration process, for low risk medical devices and IVDs; refer regulation 11.**

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

**Note: Often the manufacturers for supply of components can be many.**

"manufacturer" means –
(a) the natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD before it is placed on the market under the natural or legal person's own name, or in the name of a firm or company, regardless of whether these operations are carried out by that person by himself or on his behalf by a third party; or
(b) any other person who assembles, packages, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose/use as a medical device or IVD with a view to their being placed on the market under the person's own name, apart from a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose/use for patients, and excludes, for section 22C licensing purposes, manufacturers situated outside of the Republic, but for which medical devices and IVDs the Authorised Representative, as a section 22C license holder, remain responsible”

**Deleted ‘natural or legal’ as this is covered in the definition of a ‘person’. Addition: in many cases, the manufacturer does not perform the full process of “manufacturing”. The exclusion of manufacturers outside of South Africa from section 22C is needed to align with global approaches.**
A “manufacturer” outside South Africa would not necessarily have a “licence”. The Authorised Representative will represent safety and performance responsibility in South Africa as per the definition.

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

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

Ink and cartridge deletion as medical devices and IVD may use new technology formats

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

This term is not in the content of the regulations.

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

This term is not in the content of the regulations.

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

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

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

Remove definition, since Regulation 5’s empowering provision in Act 101 and Act 72 is not applicable to medical devices and IVDs.
"person" means both a natural and a juristic person;

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

Not used in the content of the regulations

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

Not used in the content of the regulations. Note: There is potential for overlapping and contradictory provisions under the Hazardous Substances Act and the jurisdiction of the National Regulator for Compulsory Specifications. Moreover, electromedical equipment and radiation emitting medical devices are registered with Radiation Control under the Department of Health. Duplication of regulation for the same medical devices will be onerous and inefficient.

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

Not used in the content of the regulations.

"recall" means a manufacturer’s removal or correction of a batch/batches of a marketed product that the Council considers to be in violation of the laws it administers and or may be as result of a serious adverse event. Recall does not include a market withdrawal or a stock recovery.

Addition as it is in the content of regulation 25 (a)

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

Addition: to include IVD's. Deletion because 'refurbished' does not have the same meaning as repaired, or serviced.

"reprocessed" is the disposition of an original device that has previously been used and has been subjected to additional processing for the purpose of re-use. The re-processor becomes responsible for the safety and performance of the re-processed medical device or IVD."
The inclusion of reprocessed: referred to in the definition of manufacture. Referred to in regulation 30 (2).

"Reusable medical device": Means a device intended for repeated use either on the same or different patients, with appropriate decontamination and other reprocessing between uses.

Addition; GHTF/SG1/N77:2012 – Principles of Medical Device Classification

"Reusable surgical instrument": means an instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar surgical procedures, which is intended by the manufacturer to be reused after appropriate procedures for cleaning and/or sterilisation have been carried out.

Addition; GHTF/SG1/N77:2012 - Principles of Medical Device Classification

"Self-testing" means testing performed by lay persons

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

Delete as not used in the content of the regulations and may be included as a definition and use in a guideline. The guideline should include a definition of "single patient use device" that means medical device or IVD that is intended to be used on an individual patient during a single procedure and then disposed of and which is not intended to be reprocessed and used again.

'Serious device adverse event' means any adverse event that led to any of the following:
- death,
- serious deterioration in the health of the subject, that resulted in any of the following:
  (i) life-threatening illness or injury,
  (ii) permanent impairment of a body structure or a body function,
  (iii) hospitalisation or extending the duration of hospitalisation,
  (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,
- foetal distress, foetal death or a congenital abnormality or birth defect.

Addition of serious device to distinguish it from adverse and serious adverse events as defined in Good Clinical Practice (GCP) for clinical trials (which don't have to be related to the device). In this definition only events that are related to the device need to be reported hence the need to distinguish it from the GCP definition. Source: "Proposed Amended EU IVD directive"

"Site Master File" means a document prepared by the manufacturer containing specific and factual good manufacturing practice information about the production and/or control of manufacturing operations carried out at a named site and any closely integrated operations at adjacent and nearby buildings.
Delete as this is a medicines requirement and is not applicable, as Medical Devices should follow the ISO13485 with a quality manual and certification. What is understood as GMP in pharmaceutical circles are not the same as the ISO13485 standard, which is a quality management approach designed for medical devices and IVDs. Being ISO certified means that the manufacturer / importer / distributor possesses all the necessary documentation required by the ISO standards.

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

Not used in content of regulations

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

Deletion as not used in the content of the regulations

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

Deletion as not used in the content of the regulations.

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

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

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

Delete ‘and includes a wholesale pharmacy’ as this term is not relevant to medical devices and IVDs.

"Withdrawal" means a manufacturer, importer or distributor’s removal or correction of a distributed medical device or IVD which involves a minor non-conformance that would not be subject to legal action by the Council or which involves normal stock adjustments, e.g. normal stock rotation practices, routine equipment adjustments and repairs, etc.

Addition as in the content of definitions under “Recall”
THE MANNER AND CONDITIONS FOR ALLOWING INTERNATIONAL TENDERING

[NOTE: this regulation refers to section 15C(b) which in Act 101 only applies to medicines – it can therefore not be included in the regulations as such a regulation would then be ultra vires the empowering Act. Even if it were applicable, the conditions of supply of medicines are markedly different to that applicable to devices and IVDs. Firstly, patents are not relevant (in terms of generic and patent medicine considerations), and there are many competitors providing each medical device or IVD in the market. The concern relating to possible price monopolies therefore does not apply. Secondly, there is often more than one distributor of a device or devices in the market, so the rationale for such a provision, as may be in place for medicines, does not exist for devices and IVDs. Recommend removal.]

Comments provided on this regulation are for the Regulator’s consideration, although SAMED recommends that the entire Regulation 2 be removed.

2 (1) The State may tender for a medical device or IVD internationally if such a medical device or IVD -
   a. can be obtained at a lower price outside of the Republic; or
   Caution: 2.1a: implies that any product even if it is registered in the Republic can be purchased outside the Republic if it is cheaper.
   A cheaper product sourced outside the Republic may not enjoy the same after-sales benefits as those products made available in South Africa (for example, training, software updates, maintenance, waste management, etc.). This could compromise patient safety and efficacy of a medical device or IVD and result in unintended consequences for the State healthcare system.

   b. is, in the opinion of the Minister, essential for national health.
   c. is the same as that currently available in SA
   Addition of; The product must be the same as that which is currently available in South Africa with respect to safety and performance, with the same benefits and features

(2) A medical device or IVD referred to in subregulation (1), which at the time of request for tenders is not registered, may be subjected to an expedited registration process in terms of regulation 3.
(3) A medical device or IVD cannot be procured by international tender unless such medical device or IVD is registered in terms of the Act at the date of supplying the tender goods

Addition of; ‘at the date of supplying the tender goods’ to ensure that unregistered product is not procured by tender
EXPEDITED REGISTRATION FOR MEDICAL DEVICES OR IVDs

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

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

Deletion in sub-regulation 3 (2) of 30 days, which is too long for the lifecycle of medical devices and IVDs as new models, additional variants, technological improvements may follow; Expedited process should be quick – to allow patients access [NOTE: It should not be a “no supply” case – but rather when in the interest of access to healthcare, as a constitutional criterion, there is a short supply of alternatives]

Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer

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

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

Deletion in sub-regulation 3 (4) of nine months, a period which is too long for the lifecycle of medical devices and IVDs as new models, additional variants, or technological improvements may follow; expedited process should be quick – to allow patients access. In context of the lifespan of devices, 9 months would be too long even for “normal” registration.

Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer

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

PARTICULARS TO BE PUBLISHED IN THE GAZETTE

4 The following particulars with regard to applications for registration referred to in section 15(11) shall be published in the Gazette and made available by the Council on its website:

a. the name and / or group or family, where applicable, of the medical device or IVD;
b. the name of the applicant and holder of the registration who is responsible for the product;

c. the number allocated to it in terms of section 15 of the Act;

d. the name and address of the manufacturer and manufacturing facilities;

e. the class of medical device or IVD; and

f. the nomenclature system or code of the medical device or IVD.

Section 15(11) currently does not refer to medical devices or IVDs, require Act 72 of 2008 to bring into effect.

However, if the Section did refer to medical devices, the following recommendations would apply:

Corrections of Regulation 4 to allow for publication of particulars on the Council's website; alignment with the definitions; delete 'manufacturing facilities' as there may be many. Delete regulation f. as there may be a vast number of codes.

Recommend that the term 'applicant' is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer.

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

[NOTE: this regulation refers to section 15C which in Act 101 only applies to medicines – it can therefore not be included in the regulations as such a regulation would then be ultra vires the empowering Act. The amended Act 72 also refers to medicines and not medical devices or IVD’s. Even if it were applicable, the conditions of supply of medicines are markedly different to that applicable to devices and IVDs. Firstly, patents are not relevant (in terms of generic and patent medicine considerations), and there are many competitors providing each medical device or IVD in the market. The concern relating to possible price monopolies therefore does not apply. Secondly, there is often more than one distributor of a device or devices in the market, so the rationale for such a provision, as may be in place for medicines, does not exist for devices and IVDs. Recommend removal as there is no enabling Act to support this regulation in terms of medical devices and IVD’s.]

Comments provided on this regulation are for the Regulator’s consideration, although SAMED recommends that the entire section be removed.

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

a. the medical device or IVD is being sold outside the Republic with the consent of the holder of the patent of such medical device or IVD;

b. the medical device or IVD is imported from a person licenced by a regulatory Council recognised by the Council;
c. the person desiring to import such medical device or IVD is in possession of a permit issued by the Minister (as per sub-regulation (2)); and

d. the medical device or IVD is registered in terms of the Act.

Deletion of sub-regulation (1) a. as exported products have authorised representative in the receiving country and sub-regulation (1) b as there are no permits issued by the exporting countries

Addition in sub-regulation (1) c. for reference to sub-regulation (2)

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

a. a duly completed application on a form approved and provided by the Minister;

b. a certified copy of his or her identity document or in the case of a juristic person, a certificate of registration as such in the Republic;

c. a certified copy of his, her or its registration in terms of the Pharmacy Act, 1974, where applicable the name and ID of the authorized Representative;

d. a certified copy of a licence in respect of premises in terms of section 19 of Customs and Excise Act, 1964 (Act No. 91 of 1964);

e. documentary proof

i. the medical device or IVD is under patent in the Republic;

ii. that the medical device or IVD is registered in its country of export by a regulatory Council recognised by the Council Copy of the declaration of conformity;

iii. regarding the lowest price at which the medical device or IVD is sold in the Republic;

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

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

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

Addition to sub-regulation 2 c. for the name and ID of the authorized Representative and deletion of a certified copy of his, her or its registration in terms of the Pharmacy Act, 1974 as this is not relevant to medical devices and IVD’s

Deletion of in sub- regulation 2 e) to iv), as these documents are not relevant to medical devices and IVD, and addition of a copy of the declaration of conformity

Addition in sub-regulation 5 (2) e (v) of quality management system, which should be certified and is deemed to be effective by the conformity assessment or notified body and deletion of good manufacturing and distribution practices which is relevant to medicines

(3) The Minister.

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

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

c. may cancel the permit if the holder thereof fails to comply with the conditions of the permit or on any other good cause shown.
Recommend that the term ‘applicant’ is not needed and should be removed from these regulations – by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer.

(4) The permit issued in terms of sub-regulation (3) may only be transferred with the approval of the Minister.

(5) A person issued with a permit in terms of subregulation (3) must apply to the Council for the registration as per regulation 11 of the medical device or IVD specified in the permit by submitting to the Registrar;
   a. a certified copy of that permit;
   b. a duly completed application form approved and provided by the Council; and
   c. an application fee as determined by the Council.

(6) The Council
   a. must, if satisfied that the application referred to in subregulation (5) complies with the requirements of the Act and these regulations and those of the Council regarding the safety, quality and performance of the medical device or IVD, and that its registration is in the public interest, approve the application with or without conditions; and
   b. may issue the person referred to in subregulation (5) with a certificate of registration in respect of such medical device or IVD under the name approved by the Council.

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

Deletion of contents in sub-regulation 5, 6 and 7 as medical devices and IVDs are not regulated as medicines and are controlled through conformity assessment certification and implementation of a quality management system.

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

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

IMPORTATION OF MEDICAL DEVICES AND IVDs INTO THE REPUBLIC

6. (1) No person shall import any medical device or IVD, including Medical devices or IVDs imported in terms of section 15C of the Act, read together with regulation 5, into the Republic except through one of the following ports of entry:
   a. Cape Town Airport or harbour;
   b. Port Elizabeth Airport or harbour;
   c. King Shaka International Airport or Durban harbour; and
   d. OR Thambo International Airport.

Deletion of regulation 6 (1) which refers to 15C of the Act. There is no enabling act which refers to importation of medical devices or IVDs under 15C.
A person may only import a medical device or IVD if such person:
a. is licensed in terms of the Act to import medical devices or IVDs; and
b. in the case of unregistered medical devices or IVDs, is authorised by the Council to import or use such unregistered medical devices or IVDs (for example, for compassionate use); or
c. is importing medical devices or IVDs
   (i) not required to be registered in the case of Class A medical devices and Class A and Class B IVDs
   (ii) intended to be used for pre or post market analytical performance evaluations, non-clinical research, teaching, presentation or demonstration purposes, RUO “Research use only” diagnostics, and shall be listed with the Authority before they may be imported, and where the medical device or IVD has approved ethical clearance where necessary.

Addition of regulation 6 (2) c “Research use only” diagnostics are not registered in other jurisdictions.
IVDs used for pre or post market analytical performance evaluations, non-clinical research, teaching, presentation or demonstration purposes are not eligible for registration, but will require registration if they are to be sold or used for *in vitro* diagnostic purposes.

It should also be noted that IVDs are not used in, or on the body but are used outside of the body. In most cases, there is no patient-interaction at all (i.e. a sample is taken from a patient, and analysed in a laboratory)

Chapter 9 of The National Health Act already provides for regulation under the National Health Research Committee and National Health Research Ethics Council. Exemption from registration for Class A medical devices and Class A and Class B IVDs is in line with internationally harmonised practices. Recommend that these products follow a listing process only.

Combination devices, excluding IVDs, shall be assessed and authorised in accordance with these medical device regulations.

Include sub-regulation (3) to ensure clarity for regulatory pathway for combination medical devices.

For Borderline devices, in order to decide whether a product is considered a medical device or a medicine, the following points should be considered:

a) the intended purpose of the product, taking into account the way the product is presented;
b) the method by which the principal intended action is achieved.

In the case of a medical device, the principal intended action is as defined in the definition of medical devices may contain medicinal substances which act on the body in a manner ancillary to the device. However, where such substances act in a manner that is more than ancillary, the product is regulated as a medicinal product rather than a medical device.
(3) for borderline products, the medicinal substance must be verified by equivalence to the methods required in the medicines regulations with regard to the safety, quality and performance

(4) under the classification rules as per regulation 14, such a device would fall into class D

a) the Conformity Assessment Body carrying out relevant conformity assessment procedures in respect of such a device must consult with the medicines regulator, where appropriate, on the medicinal aspects of the device.

Included regulation for Borderline medical devices to assist with regulatory clarity.

TRANSMISSION OF MEDICAL DEVICES OR IVDS THROUGH THE REPUBLIC

7. (1) Medical devices and IVDs that are transmitted through the Republic shall-
   a. while in the Republic be stored in a bonded warehouse which is registered with the Council; and
   b. not be manipulated while in the bonded warehouse unless authorised by the Council.

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

Correction of regulation 7 (2) as the manufacturer determines the storage condition

Council to clarify that bonded warehouses are only for products that move through South Africa for export and which are not sold or marketed in South Africa.

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

8. (1) A person referred to in section 22C (1) (b) of the Act
   a. must prior to commencing business as such
   i. apply to the Council for a manufacturer licence to manufacture or, import or export medical devices or IVDs or a wholesale licence to act as wholesaler or distribute medical devices or IVDs;

Deletion in sub-regulation 8 (1) a i) “export”; Exported devices follow the regulatory requirements of the country of destination; such devices will not be used in South Africa and are therefore not subject to South African medical device regulations. If an exporter is made subject to South African regulations this could result in relabeling in the receiving country.

ii appoint, and designate as such an authorised representative who will control the manufacturing and or distribution of medical devices or IVDs;
iii appoint and designate a natural person who resides in the Republic, who shall be responsible to the Council for compliance with the Act;

Deletion of sub-regulation 8 (1) a (iii) as the "holder of a certificate of registration" (HCR) is responsible as per the definition "means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medical device or IVD including quality and safety and compliance with conditions of registration;"

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

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

i. the particulars of the owner of the business;
ii. the particulars of the authorised representative;
iii. registration of a pharmacist where applicable;
iv. qualifications of staff to manufacture, store, distribute, sell, maintain or repair medical devices or IVDs in terms of the Act;
v. the ability to comply with good manufacturing or distribution practices as determined by Council a quality management system, which must include: a recognised quality management system

aa. a copy of a local area plan of the location of the business premises indicating all adjacent properties and the nature of the business being conducted, on such properties;
bb. a floor plan of the building in which the business premises are situated;
c. a plan of the actual layout of the business premises;
dd. an inventory of equipment to be used in conducting the business;
e. a manual of procedures and practices to be implemented to ensure the safety, quality and performance of medical devices or IVDs to be manufactured or distributed and sold, including a procedure for recording all entities to whom a medical device or IVD has been distributed, or in the case of a wholesaler or distributor, the record of the entity that has supplied them with the medical device or IVD. The procedure should include a requirement that such records be maintained for a period of at least five years after the distribution of the last medical device or IVD of a kind.

Deletion of sub-regulations 8. (1) c (iii) and (iv) as these regulations are applicable to medicines and are not relevant to medical devices, which follow the ISO13485 standard: “Medical devices -- Quality management systems -- Requirements for regulatory purposes”

Reference to a quality management system in sub-regulation 8 (1) c (vi) which should be certified and is deemed to be effective by the conformity assessment or notified body and deletion of 'good manufacturing and distribution practices', which is relevant to medicine.

Deletion of sub-regulation 8. (1) c vi. aa-ee as these would form part of the dossier reviewed by
d. must specify the medical devices or IVDs or group or family of medical devices or IVDs to be manufactured, imported, exported or distributed and sold;

Addition in sub - regulation 8. (1) d) for a group or family

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

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

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

Addition in sub - regulation 8. (3) of may and deletion of must as it may be not necessary for Council to inspect premises where a quality management system has been certified and is deemed to be effective by the conformity assessment or notified body

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

Addition in sub-regulation 8 (4) c of quality management system, which should be certified and is deemed to be effective by the conformity assessment or notified body and deletion of good manufacturing and distribution practices which is relevant to medicines

Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer

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

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

(7) A licensee must notify the Registrar in writing of any change to any of the particulars furnished in the application or entered in the register, which occurs after the issue of the licence.
(8) Any entry into the register which is proved to the satisfaction of the Council to have been made in error or through misrepresentation or in circumstances not authorised by the Act, may be removed from the register.

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

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

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

9 (1) A licence issued in terms of regulation 8 shall be valid for a period of 5 years from the date of issue and may be renewed in terms of sub-regulation (3).

(2) A licence referred to in sub-regulation (1) which has expired may be renewed by application to the Council in the event that the date for renewal has been missed

(3) An application for renewal referred to in sub-regulation (2) shall -
   a. contain at least the information or documentation referred to in regulation 8(1)(c), as the case may be;
   b. be accompanied by a prescribed fee; and
   c. be made at least 90 days before the expiry of the existing licence.

Additions to sub-regulation 9 (1) for provision of renewal of a licence; Additions to sub-regulation 9 (2) in the event that dates are missed and a new application is not required

APPEAL AGAINST THE DECISION OF THE COUNCIL

The empowering provision, section 24 of Act 101 of 1965, is significantly changed by Act 72 of 2008, and if Act 72 of 2008 comes into effect, these regulations, and SAMED’s comments thereto, would similarly change significantly.

10 (1) An appeal to be lodged or representations to be made in terms of Section 24 of the Act against a decision of the Council, shall be lodged or made within 30 days from the date on which the decision appealed against or in respect of which representations are made was communicated to the appellant or person making representations, unless the decision has been the subject of an application under the Promotion of Access to Information Act, Act 2 of 2000, in which case the appeal would be lodged within 30 days of such information being made available by the Council to the applicant.
(2) In lodging the appeal or making representations, the appellant or person making representations shall send a notice by registered mail to the Minister, for attention the Registrar, Medicines Control Council, Private Bag X828, Pretoria, 0001, or by any form of communication, and the Registrar shall acknowledge receipt of such communication of a notice of appeal within 2 days after receipt thereof.

It must be noted that sending letters per registered post are no longer deemed to be proof of receipt, and it is submitted that electronic appeals should be accepted, as well as hand-delivered and signed for appeals.

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

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

(5) The appeal committee -

x. shall be chaired by a legal practitioner and, in addition, comprise of at least two persons who are familiar with the medical devices or IVDs, as the case may be, and/or who are familiar with medical devices or IVD regulatory frameworks and/or the medical devices or IVD market, as the case may be:

a. shall determine the procedure for its hearings, in compliance with the Promotion of Administrative Justice Act, Act 2 of 2000;

xx. ensure that a hearing is conducted as soon as possible, but no longer than 60 days after its appointment

Sub-regulation xx is proposed in order to avoid undue delays in scheduling the appeal hearing. Such delays would defeat the purpose of an internal appeal process, which should be fast and efficient.

b. may, if it deems necessary call for oral evidence or argument or summon any person who-

i. in its opinion may be able to give information concerning the subject of the appeal; or

ii. it believes has in his or her possession or under control any document which has a bearing on the subject of the appeal, to appear before it at a time and place specified in the summons, to be asked questions or to produce any document; and

d. shall, if it calls for oral evidence or argument,

i. determine the date, time and place for the appeal and shall communicate these in writing to the appellant and the Council;

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

(6) Persons appearing before the Appeal Committee may be represented by a legal practitioner.
The appeal committee shall consider the appeal and make a decision in regard thereto within a period of 30 days from the date -
  a. on which it was appointed; or,
  b. when the appeal hearing was completed, whichever is the later.

Failure to comply with the provisions of this regulation is subject to review by a competent body and/or entitles the appellant to approach any appropriate body or forum without being required to have exhausted the provisions of this regulation.

Addition of (8) included to protect the appellant from non-action or inappropriate action by the Appeal Committee

APPLICATION FOR LISTING OR REGISTRATION OF A MEDICAL DEVICE OR IVD

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

(a) All Class A medical devices and Class A and Class B IVDs shall be exempted from registration and shall be listed with the Authority in terms of such call up notices before they may be imported, manufactured, sold or used in the Republic.

Addition to sub-regulation 11 (1) (a) for exemption of registration on Class A medical devices and Class A and Class B IVDs in line with internationally harmonised practices and make provision for listing of non-registered devices

(b) An application for the listing of a medical device or IVD shall be submitted on the prescribed form as determined by Council.

Addition to sub-regulation 11 (1) (b) for provision for an application form

(2) The application referred to sub-regulation (1) shall include the particulars of the natural person who shall be responsible for communication with the Council.

Delete as already included in the definition of Holder of Certificate of Registration.

(3) A registration application referred to in sub-regulation (1) shall be made on the appropriate form obtainable from the Registrar and shall be accompanied by:
  a. a properly completed screening index/summary/contents form obtainable from the Registrar;

Amendment to sub-regulation 11 (3) (a) as a screening form is used for medicines and is not relevant to medical devices and IVDs where the screening form and registration application is the same document.
b. a proposed label for use on the medical device or IVD, if applicable;
c. where applicable,
   i. a copy of the quality management system certificate
   ii. a copy of the manufacturer licence together with the current Good Manufacturing
       Practice certificate from the regulatory authority from the country of origin of the
       medical device or IVD, as the case may be;

Addition in sub-regulation 11 (3) c (i) of quality management system, which should be certified and
deemed to be effective by the conformity assessment or notified body; deletion of good manufacturing
practice certificate which is relevant to medicines

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

Deletion of sub-regulation 11 (3) c (iii) of certified copy of the manufacturer’s evidence as the evidence
is the conformity assessment certificate and quality management system certification

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

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

Deletion of sub-regulation 11 (3) d, e and f as these requirements are covered by the conformity
assessment certificate and quality management system certification

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

g. the application fee.

(x) Council will review the application and reach a decision regarding the application within 90
   calendar days. In processing applications, the Council must adhere to the following timelines
   after receiving an application:
   i) a letter acknowledging receipt of application shall be sent within 7 days
   ii) a letter confirming that the application has been reviewed for acceptance in the
       registration process shall be sent within 14 days
   iii) a letter confirming the registration decision shall be sent within 60 days
   iv) registration approval and issue of the registration certificate shall be completed
       within 90 days

Addition of sub-regulation 11 (x) to define timelines for registration to enable a mutually
acceptable timeline for registration that accommodates the lifecycle periods of devices, in the
technology and uses, that is very different to medicines.
(4) All information referred to in sub-regulation (3) shall be at least in English.

(5) The application form for listing referred to in sub-regulation (1) b and for registration referred to in sub-regulation (3) shall contain at least the following information:

a. Particulars of the Applicant and the prospective Holder of the Certificate of Registration:
   i. Name;
   ii. Business Address;
   iii. Postal Address;
   iv. Telephone Number;
   v. Fax Number;
   vi. e-mail address; and
   vii. Contact details of the person referred to in sub-regulation (2) in the case of a juristic person.

Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer.

Sub-regulation (2) is deleted.

b. particulars of the device or IVD:
   i. name, make and model where applicable; the name and / or group or family, make and model of the medical device or IVD where applicable;
   ii. intended purpose or use;

Addition of sub-regulation 11 (5) b (ii) as the intended use is common terminology for medical devices internationally

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

Deletion of sub-regulation 11 (5) b (iii) as this is not applicable to medical devices, which have a supply chain that is not the same as for medicines; Addition of manufacturer for alignment to definition

iv. classification in all countries where registered and proposed classification in South Africa, and approvals in recognised authorities outside the Republic;

Change to sub-regulation 11 (5) b (iv) as not all devices are registered
iv. classification in all countries where registered and proposed classification in South Africa;

v. nomenclature system code;

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

Deletion in sub-regulation 11 (5) b (vi) as the substance in the medical device is not therapeutic and it may not be scheduled. Addition of medicinal substance to align with definition.

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

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

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

Note: Guideline required for Essential Principles

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

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

a. a copy of certificate of registration where applicable;

b. package insert or instructions for use where applicable;

c. conditions of registration; and

d. any other information as determined by the Council

The Council will provide a list of approved notified bodies both in South Africa and other countries to allow for recognition of international certifications

Deletion in sub-regulation 11 (8): medical devices are not registered internationally and the criteria for the application is listed above in sub regulation 5 that applies to both locally manufactured and imported medical devices

Change to sub-regulation (8) to provide for regulatory recognition of notified body conformity assessment certifications

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

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

Note: Alignment to regulation 11

a. the name, make and model, where applicable, of the medical device or IVD and / or group or family;
b. the registration number allocated to the medical device or IVD;

c. in the case of a combination medical device the name of the medicinal substance of each active ingredient of the medical device and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medical device;

Deletion in sub-regulation 12 c) as combination devices do not contain active ingredients. The intended purpose or use of the device is what defines the product as a medical device, per the definitions.

d. the intended purpose or use of the medical device or IVD;

Correction in sub-regulation 12 d) for alignment to definition to intended purpose or use

e. the name of the applicant and the holder of the certificate of registration;

f. the name and address of the manufacturer and the manufacturing facilities;

Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer

Delete facilities as these may be numerous within the process of manufacture.

g. the date of registration of the medical device or IVD;

h. the conditions of registration of the medical device or IVD determined in terms of section 15(7) of the Act;

Section 15(7) of the Act does not pertain to medical devices.

i. the class of medical device or IVD; and

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

AMENDMENT TO THE MEDICAL DEVICE AND IVD REGISTER

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

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

a. the registration number of the medical device or IVD;

b. the name and business address of the authorised representative or manufacturer applicant;

c. declaration by the applicant authorised representative or manufacturer that the information furnished is complete and accurate;

d. the details of the amendment applied for;

e. the manufacturer licence number of the manufacturer; and

f. any other information as determined by the Council.
Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer.

CLASSIFICATION OF MEDICAL DEVICES AND IVDs

14 (1) The following are the classes of medical devices and IVDs, as determined by the manufacturer, as defined by the classification rules issued by Council -

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

where risk relates to the patient or to public health.

Addition in sub-regulation 14 (1) International practice is that the manufacturer determines the classification as determined from classification rules, which will be need to be issued by Council

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

Addition in sub-regulation 14 (2) As per regulation 11 All Class A medical devices and Class A and Class B IVDs should be listed.

(3) The classification of medical devices and IVDs shall be as determined by Council the manufacturer in accordance with the technical classification rules as annexed to the Regulations marked (Annexure A).

Correction in sub-regulation 14 (3) for the word classification to be in alignment with regulation (1) Reference the classification rules from GHTF in GHTF/SG1/N77:2012 “Principles of Medical Devices Classification” and include content as Annexure A.

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

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

Amendment of sub-regulation 14 (4) and deletion of sub-regulation 14 (5) to be in alignment with the recommendations for sub-regulation 14 (1) above.
REGISTRATION CERTIFICATE

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

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

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

1. Name…
2. Registration number…
3. Class of medical device or IVD…
4. In the case of combination medical devices the name of the medicinal substance and the non-medicinal substances and the quantities thereof per dosage unit or per suitable mass or volume or unit of the medical device or reagent of an IVD as the case may be approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume or unit of the medical device or reagent of an IVD as the case may be

Deletion in sub-regulation 15 4 as per regulation 12: Combination devices do not contain active ingredients. The intended purpose or use of the device is what defines the product as a medical device, per the definitions.

5. Nomenclature system or code…
6. Conditions under which the medical device or IVD is registered…
7. Registered in the name of (holder of certificate of registration)…
8. Name and address of the manufacturer and the manufacturing facility…

Deletion in sub-regulation 15 8. as per regulation 12: delete facilities as these may be numerous within the process of manufacture

9. Date of registration…
Registrar
Issued at…… on…..20…

DESTRUCTION OF MEDICAL DEVICES OR IVDs

16 (1) No medical devices or IVDs may be disposed of as per the labelled instructions into municipal sewerage systems or as required by national- and provincial legislation, where relevant.
(2) The destruction or disposal of medical devices or IVDs must be conducted in such a manner as determined by the Council to ensure that they are not retrievable or cannot be reused or reassembled.

Deletion in Regulation 16: Remove “no” and delete municipal sewerage systems as Medical devices are not medicines that are “ingested, inject or applied”. The instructions for use provide disposal advice.

Where relevant added as some Class 1 devices may be disposed via the general domestic waste system but all other devices and IVDs need to follow the following legislation:
Regulations published under the National Health Act for general- and medical waste; the Hazardous Substances Act; and/or the National Environment Management: Waste Act

Provincial legislation, where it exists (e.g. in Western Cape).

**PARTICULARS FOR A PRESCRIPTION OR ORDER FOR A MEDICAL DEVICE**

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

a. the name, qualification, practice number and address of the prescriber or authorised person placing the order;

b. the name and address of the patient in the case of a prescription or the name and address of the person to whom the medical device is delivered in the case of a prescription issued by a veterinarian;

c. the date of issue of the prescription or order;

d. the name of the medical device(s); and

e. the number of times the prescription or order may be repeated.

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

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

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

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

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

Deletion of Regulation 17 as this transcript of Regulation 28 of the medicines regulations is not appropriate or relevant to medical devices. Combination devices contain a substance, which is to be approved by Council, but which still does not make the device subject to medicines- and section 22A rules. All devices follow the quality management system control for distribution and sale, especially in regards to identification and traceability.

Devices are generally not prescribed, with prescription, and may be made available per instructions for use. Some medical devices are designed to be used by lay persons while others can only be used by a trained health care practitioner or health facility personnel. Access to medical devices depends on the conformity assessment requirements related to classification or requirement of the competent authority / regulator, as a condition of registration, which follows international practice.
These comments apply to all the draft regulations that refer to “scheduled substances”:

If accepted, South Africa would be globally unique and introduce provisions that would have no rational or practical basis, apart from being based on a medicines-approach. No risk is posed to patients where scheduled substances form part of a device, and unlike a medicine, in most cases, combination devices are not taken home by patients, and if so, the quantity of scheduled substance is too little to have any effect. It is also, for the most part, used under direct supervision of, by, or with the assistance of a healthcare professional.

The various references on scheduled substances, and the need for prescriptions, returns and registers do not apply to medical devices and IVDs. Section 22A, which would be the empowering provision does not apply to devices, which includes combination devices under the definition of a device in Act 101 of 1965, and in Act 72 of 2008.

To control these scheduled substances if they appear in devices in the same manner as if they are in a medicine, does not make sense. The reason for that is that the scheduled substance on or in the device is an accessory, and does not fulfil the function that it does as a medicine. The quantity of scheduled substance on or in a device is also very low, and no risk is placed on the patient for possible abuse, etc. The dosage form is markedly different. Furthermore, these combination devices are used by healthcare professionals, and to require it to be treated as if it was a medicine, where an “order” was needed prior to a patient being able to access it, makes no practical or logical sense.

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

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

b. the quantity of such substance, as a raw material or as contained in a medical device or IVD which was held in stock on 1 January of the preceding calendar year;

b. the quantity of such substance acquired during the preceding calendar year when contained in a medical device or IVD;

c. the quantity of such substance contained in a medical device or IVD, which were disposed of during the preceding calendar year through:

i. exportation; or

ii. destruction thereof;

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

(4) Notwithstanding sub-regulation (1), the Council may exempt an importer or exporter from furnishing a return, if the particular return is not necessary in determining the consumption of any of the substances included therein.

(5) The return referred to in sub-regulation (1) must comply with the following requirements:

b. all quantities must be expressed in metric units as a percentage base of the relevant substance.
b. in the case of medical devices or IVDs containing opium, quantities must be expressed in terms of opium containing 10% of anhydrous morphine;
c. medical devices or IVDs containing preparations obtained not directly from opium itself but by mixing opium alkaloids must be expressed in terms of morphine; and

d. where stocks are held or manufacture has been undertaken on behalf of another applicant, this fact must be indicated.

Deletion of Regulation 18 as this transcript of Regulation 29 of the medicines regulations is not appropriate or relevant to medical devices.

Any scheduled substance that falls within the definition of a medicine must follow the medicines regulations; correspondingly a substance ancillary to a medical device follows device regulations.

See comments above under Regulation 17

REGISTER OF SPECIFIED SCHEDULES 5, SCHEDULE 5 AND 6 MEDICAL DEVICES AND IVDs

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

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

a. the date on which the medical device or IVD was received or supplied;
b. the name, business address of the person from whom the medical device or IVD was received or sent and in the case of an imported medical device or IVD, the import permit number;
c. the name and address of the person who purchased the medical device or IVD;
d. the quantity in words and figures of such medical device or IVD;
e. in the case of the supply of the medical device or IVD on prescription, the name and address of the authorised prescriber unless such prescription was issued at a hospital in which case the name of the authorised prescriber shall be recorded;
f. the quantity of the substance used during the manufacturing process of a medical device or IVD; and

g. any other information as the Council may determine.

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

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

(5) Records must be stored in an orderly manner so that they can be accessed easily.
Deletion of Regulation 19 as this transcript of Regulation 29 of the medicines regulations is neither appropriate nor relevant to medical devices. Combination devices contain a substance, which is to be reviewed by Council.

Any scheduled substance that falls within the definition of a medicine must follow the medicines regulations; correspondingly a substance ancillary to a medical device follows device regulations.

See comments above under Regulation 17

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

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

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

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

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

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

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

Note: In many cases a sample will not be practical and testing inaccessible and could be costly for large and sophisticated medical equipment.
SEIZURE OF MEDICAL DEVICES OR IVDs

21 (1) A medical device or IVD may be seized if it-
   a. is unregistered and sold in contravention of the Act;
   b. is suspected counterfeit;
   c. is misbranded;
   d. has expired;
   e. is suspected stolen;
   f. is Scheduled and is possessed by an unauthorised person or by an authorised
      person but in unauthorised quantities;
   g. has been declared undesirable in terms of the Act;
   h. belongs to the State and is found possessed by an unauthorised person;
      or
   i. is used in unauthorised clinical trial or investigation.

(2) An inspector seizing any item in terms of section 28 (1)(c) of the Act shall as soon as
     possible and at the scene of seizure make a written inventory of all items seized and the
     inventory shall include:
     a. the date, place and time of seizure;
     b. the name and personal details of the person from whom the items were seized;
     c. the name and quantity of every item seized; and
     d. the name of the inspector conducting the seizure.

(3) An item contemplated in section 28 (1) (c) of the Act may be used as evidence in any
     criminal proceedings in terms of this Act.

(4) An inspector taking any sample in terms of section 28 (1) (d) shall make a written
     inventory of all samples taken which shall include:
     a. the date on which, the place where and time when the sample was taken;
     b. a description of nature and size of each sample taken;
     c. the personal details of the person in whose presence the samples were taken;
     and
     d. the name of the inspector taking the sample.

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

(6) No person may, without the permission of the Council, continue to use, destroy, remove,
     cause or permit to be removed any medical device or IVD that has been seized and
     placed under an embargo.
(7) The Council shall safely dispose of any condemned seized medical devices or IVDs in accordance with regulation 16.

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

Note: This transcript of Regulation 32 of the medicines regulations is not entirely appropriate or relevant to medical devices e.g. sub-regulation 21 1f.

Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer

CONDUCT OF CLINICAL TRIALS AND INVESTIGATIONS

The Health Act Chapter 9 already provides for the National Health Research Committee and National Health Research Ethics Council which currently regulates and controls clinical trials and IVD investigations. Duplication of regulation would be undesirable. The recommended approach here is that clinical trials require Ethics Committee authorisation. Council should be notified of proposed clinical trials so that importing medical devices for clinical trials may proceed without hindrance.

22 (1) A person desiring to initiate or conduct a clinical trial or clinical investigation in respect of an unregistered medical device or performance assessment for an IVD, or a new intended purpose of a registered medical device or IVD, for class C and D devices as per the classification rules shall apply to the Council on a form determined by the Council for authorization to bring the device into the country to conduct such a clinical trial or clinical investigation. For a new intended purpose or use of a registered Medical Device or IVD, notification only will be required.

Deletions and additions in sub-regulation 22 (1) as this transcript of Regulation 34 of the medicines regulations is not entirely appropriate or relevant to medical devices

Included the word “clinical” to be more specific.

For Devices already registered, Council should be notified only. There should not be a requirement for Council to authorise a clinical trial or investigation as Council must not duplicate the work of ethics committees. Duplication of oversight will affect capacity at the Regulator. The notification should have to be done only after ethics committee approval, but should be allowed in parallel.

Ethics Committee (EC) approval requirements typically include:

- Protocol
- Protocol Summary
- EC checklist
- Per Investigator: CV/MPS/HPCSA/GCP certificate
- Declaration by trialist
- Investigator Brochure
- Letter to MCC (Notification, not approval)
- Sponsor Insurance
- NHREC application
- Financial agreement

In the case of Class C and D unregistered devices, only after approval from the relevant ethics committee and if no objections are received from Council and if Council authorises that the devices may be brought into the country for clinical research purposes, may the device be imported and research done.

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

Amended sub-regulation 22 (2)  Amended to concur with sub-regulation 1

a. clinical investigation plan or trial protocol;

Amended sub-regulation 22 (2) a  to concur with sub-regulation 1 and added the word plan

b. 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;

Additions in sub-regulation 22 (2) b: added wording 'where applicable', as in some instances it may not be applicable.

Deleted reference to animals as animal studies should not be included in the scope of clinical investigation of medical devices or IVDs for human use

c. Curriculum Vitae of all investigators;

d. signed declaration by the applicant and all investigators that they are familiar with and understand the protocol and will comply with Good Clinical Practice as determined by Council, internationally recognised standards and or the Council in the conduct of the clinical investigation /clinical trial;

Additions in sub-regulation 22 (2) d; There are international standards relating to Medical Device Clinical studies, reference to these should also be included.

e. informed consent document(s) and endorsement by any ethics committee recognised by the Council; and

Additions in sub-regulation 22 (2) e;  Added plural
f. name and address of the institution where the clinical trial or clinical investigation will be conducted.

Amended sub-regulation 22(2) f to concur with sub-regulation 1

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

Addition in sub-regulation 22 (3) of plan to concur with 2a

| a. number of human or animal subjects to be involved in the investigation of trial; |
| Deletion in sub-regulation 22 (3) a; Deleted reference to animals as animal studies should not be included in the scope of clinical investigation of medical devices or IVDs for human use |
| b. the name of an investigator who shall be an appropriately qualified and competent person approved by the Council, resident in the Republic, and must be in charge of the site where trials are conducted; |
| c. quantity of the investigational medical device or IVD units to be used in the trial; |
| d. information in respect of the design, manufacture and expected performance of the medical device or IVD; and |
| e. any other information as determined by the Council. |

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

(5) No person shall conduct clinical investigations or clinical trials referred to in sub-regulation (1) without the authorisation of the Council for Class C and D as determined by the risk classification rules.

This is an opportunity not to over-regulate the study process of medical devices or IVDs and encourage clinical research in this market. A proof of submission with a commencement date after 30 days of no response should be sufficient for low risk medical devices or IVD’s.

This is also an opportunity for Council not to overburden itself with administrative requirements, considering that there is an additional parallel application to the Ethics Committee for clinical investigations or clinical trials.

(6) The person conducting the clinical investigation or clinical trial must:

| a. submit progress reports to the Council after every clinical phase six months from the date when the clinical investigation or trial was started as detailed in the clinical investigation plan or clinical trial protocol and 30 days after the completion or termination of the clinical investigation or trial; |
| There may not be any updates every six months so there will be nothing to report. 30 days after completion of the study does not allow enough time to compile a final report. |
b. submit within 30 days after the completion or termination of the study an end
acknowledgement report to the Council. The report shall include adverse event reports that
occurred during the study.

c. submit serious adverse event reports within time frames to be stipulated by the Council
immediately or as soon as practically possible to the Council;
d. submit clinical investigation close out reports as soon as practically possible to the Council.

Additions/amendments of sub-regulation 22(6) b c and d to clarify reporting requirements and
make these more practical.

(7) The Council may request additional information, inspect a clinical investigation or trial or
withdraw the authorisation to conduct a clinical investigation or trial if the Council is of the opinion
that the safety of the subjects of the investigation or trial is compromised, or that the
scientific reasons for conducting the investigation or trial have changed, without prior
approval of the Ethics Committee and the Council.

Additions in sub-regulation 22 (7): Deviations from original clinical investigation plan (CIP) do
occur - these deviations from CIP can be made subject to approval and this sub regulation needs
to cater for that. Clinical investigations can be suspended by the manufacturer / regulator with a
rationale that the scientific scope of the clinical investigation has changed (e.g. additional clinical
indication or change in target populations).

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

a. clinical investigation or trial to be carried out;
b. medical device or IVD to be used for the conduct of the clinical investigation or trial;
c. persons or animal species on whom the medical device or IVD is to be used; and

d. name(s) and address(es) of the premises where the clinical investigation or trial is to be
carried out.

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

a) Intended purpose or use of the investigational device in the proposed clinical
investigation.
b) The populations and indications for which the investigational device is intended.
c) Name or number of the model/type, including software version and accessories, if any, to
permit full identification.
d) Description as to how traceability shall be achieved during and after the clinical
investigation, for example by assignment of lot numbers, batch numbers or serial
numbers.
e) The medical device or IVD shall where practical be labelled with the name(s) and
address(es) of the premises where the clinical investigation or trial is to be carried out
and a label indicating its intended use “for investigational use”.
Change in sub-regulation 22 (8); The requirements of sub regulation 8 are not practical. Labelling requirements should propose the label includes statement “for investigational use or something similar”. Council should revise above sub regulation to a traceability requirement.

This could potentially limit the amount of clinical research being conducted in SA. A replacement based on ISO 14155 (“Clinical investigation of medical devices for human subjects -- Good clinical practice”) is proposed.

(9) Any authorisation for the conduct of a clinical investigation or clinical trial by the Council may be made subject to such conditions as determined by the Council and should be completed within 45 days from the date of application to conduct a clinical investigation or clinical trial.

Additions in sub-regulation 22 (9) as there are no time lines stipulated for approval of clinical investigation requests. Time lines should be stipulated and or a period within which studies may commence.

SKILLS OF MEMBERS OF THE COUNCIL AND ITS COMMITTEES OF THE COUNCIL

Delete the reference to the Council will be the criteria is defined in the Act. It is not clear here on whether the Council is MCC or a specific Medical Device and IVD Council

23 (1) The Council shall establish medical device and IVD committees, to investigate and report to the Council, with appropriate members with relevant skills and knowledge related to the field of practice for the intended use of medical devices or IVDs which can include as required at least one biomedical engineer, one clinical engineer, one general surgeon, one cardiovascular surgeon and one orthopaedic surgeon who by qualification and experience have the necessary general and specialist surgical, clinical and biomedical knowledge and skills.

Change in sub-regulation 23 (1); The Council and any committees it establishes cannot be restricted in their membership to specific healthcare fields because of the diversity and variation of medical devices and IVDs e.g. a cardiologist is not necessarily skilled in wound care, pathologists are generally related to IVDs and microbiologists are related to sterile products.

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

Deletion of sub-regulation 23 (2); This transcript of Regulation 35 of the medicines regulations is not appropriate or relevant to medical devices. Sub-regulation 2 is deleted as this is covered by recommended amendments in regulation 1.
SERIOUS DEVICE ADVERSE EVENTS REPORTING

Heading alignment to definitions in regulation (1) with the addition of serious device

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

Addition to sub-regulation 24 (1); to include serious device adverse events as per definitions

Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer

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

Deletion in sub-regulation 24 (2) of section 15C of the Act as it is only relevant to medicines.

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

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

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

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

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

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

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

Addition to sub-regulation 24 (3); to include serious device adverse events as per definitions

Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer
(4) Nothing in this regulation shall be interpreted as prohibiting any person from reporting any serious device adverse event to the Council.

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

Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer.

Addition to sub-regulation 24 (4) and (5); to include serious device adverse events as per definitions. Included the term “user” rather than the inappropriate transcribed wording from Regulation 37 of the medicines regulations, and for alignment with definition of user.

Note that Council is required to provide a guideline on the process of reporting and the time frames required.

INVESTIGATIONS

25. The Council may conduct an investigation with regard to a medical device, its manufacturer, distributor, importer, exporter or wholesaler if, the same device is also sold in South Africa.

This regulation cannot be applicable to medical devices and IVDs not sold in South Africa.

a. such a medical device or IVD is recalled in South Africa or any other country;
b. an adverse event is reported in South Africa or any other country;
c. the medical device or IVD is suspected or found not to comply with the requirements of the Act;
d. there is an international alert with regard to such a medical device, IVD or the manufacturer of a medical device or IVD; or

This transcript of Regulation 39 of the medicines regulations may not appropriate nor relevant to medical devices.

OFFENCES AND PENALTIES

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

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

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

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

Regulation 19 deleted

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

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

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

Regulation 17 deleted

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

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

or

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

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

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

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

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

Note: Regulation 27 does not mention compliance to essential principles as it mentions compliance with standards and specifications in the registration. [Refer to Regulation 27]

s. Regulation 24 with regard to reporting of Adverse Events shall be guilty of an offence and upon conviction be liable to a fine, or to imprisonment for a period not exceeding 10 years.

COMPLIANCE WITH REGULATIONS

Heading does not correlate to the regulation that requires compliance with the “standards and specifications”

This transcript of Regulation 43 “compliance with requirements” of the medicines regulations is not appropriate to medical devices, where the declaration of conformity establishes the intended use.

Essential principles provide assurance for safety and performance of the medical device or IVD
27 (1) Every medical device or IVD shall comply with the standards and specifications, the essential principles that provide assurance for safety and performance of the medical device or IVD which were furnished to the Council within a Declaration of Conformity on the form prescribed by regulation 11 which have been accepted by the Council with regard to the registration of such medical device or IVD.

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

Amendment/deletion of sub-regulation 27 (1) and (2) as many devices do not have defined "standards and specifications" as per medicines. Medical devices and IVDs conform to the essential principles that provide assurance for safety and performance of the medical device or IVD as covered in a Declaration of Conformity.

Delete subregulation (2) as deviations and changes are managed within the quality management system and conformity assessment certification process.

BATCH RELEASE FOR PRIORITY IVDs

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

Changes to sub-regulation 28 (1): This transcript of Regulation 28 of the medicines regulations is not entirely appropriate or relevant to IVDs. Some IVD samples may be impossible to supply (e.g. large scale laboratory equipment), but would have conformity assessment certificates.

ADVERTISING OF MEDICAL DEVICES OR IVDs

Note; This transcript of Regulation 29 of the medicines regulations is not appropriate or relevant to medical devices. The supply chain for medical devices differs from medicines. Instructions for use direct who and how to use medical devices and IVDs, and are different from package inserts for medicines. Direct to consumer advertising of medical devices and IVDs will not promote self-therapy.

29 (1) Any medical device or IVD intended for use by patients, can be advertised as deemed appropriate according to its intended use and user. The under mentioned requirements shall apply to any advertisement of a medical device or IVD.

Deletions in sub-regulations 29 (1) see note preceding Regulation 29.
(2) a Medical devices or IVDs, which do not contain a scheduled substance and medical devices or IVDs which contain a substance appearing in Schedule 0 or Schedule 1 may be advertised to the public; and  

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

Deletions in sub-regulations 29 (2) as scheduled substances and scheduling is not applicable to medical devices and IVDs

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

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

a. the name of such medical device or IVD;  
b. the approved name and quantity of each active ingredient of such medical device or IVD where applicable in lettering having minimum legibility;  
c. in the case—  
i of a registered medical device or IVD, the registration number allocated to it in terms of section 15 (6);  
ii of a medical device or IVD in respect of which an application for registration has been submitted in terms of section 14 of the Act, the reference number allocated to such application by the Registrar, followed by the words 'Act 101/1965';  

5 In the case of an advertisement for a medical device which contains more than one active ingredient, no specific reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the Council for inclusion in the approved instructions for use of such medical device or IVD.

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

Deletions in sub-regulations 29 (4 5 and 6) - see note preceding Regulation 29.
LABELLING FOR MEDICAL DEVICES OR IVDs

30 (1) The label of each medical device or IVD should contain the following particulars in at least English or internationally recognized symbols, where applicable, which must appear on the medical device or IVD itself, or on the packaging of each unit, or on the packaging of multiple devices or IVDs or via an accessible electronic format:

ISO15223-1 International standard for symbols used for medical device labeling
Make provision for electronic labelling where applicable.

(a) name or trade name of the medical device or IVD;
(b) product description of intended use, approved intended purpose where practical for use of the medical device or IVD –

Correction to sub-regulation 30 (1) b to covers all possibilities for device labelling

(c) product catalogue code, where applicable;
(d) name and business address of the manufacturer;
(e) name and business address of the applicant authorised representative

Deletion in sub-regulation 30 (1) e, of applicant and addition of authorised representative in line with the defined responsibilities in the regulation (1) definition
Recommend that the term ‘applicant’ is not needed and should be removed from these regulations - by definition, the Holder of the Certificate of Registration is responsible for medical device safety, and can be the authorised representative or manufacturer.

(f) where appropriate, an indication that the device contains or incorporates a Scheduled medicinal or biological substance
Deletion in sub-regulation 30 (1) f of scheduled medicine as substances are listed as medicinal or biological in GHTF documents

(g) the lot and/ or serial number, where applicable;

(h) the serial number, where applicable;
Deletion in sub-regulation 30 (1) h, refer (g)

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

(j) the expiry date, where applicable;

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

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

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

(n) where relevant not obvious, 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;

Deletion in sub-regulation 30 (1) n, of relevant and addition of not obvious as some device equipment is obvious that the unit is single
(o) warnings or precautions, where applicable
(p) the performance intended where applicable;

Deletion in sub-regulation 30 (1) p, as addressed in sub regulation (b)

(q) where appropriate, an indication that the device is intended for:
(i) single use;
(ii) clinical investigation or premarket performance evaluation;
(iii) non-clinical research, teaching or testing purposes;
(iv) presentation or demonstration purposes; and/or
(v) in vitro diagnostic use,

(2) If the medical device is a reprocessed medical device the label must state the name of
the reprocessor and identify the medical device as a reprocessed medical device.
(3) If the IVD kit includes individual reagents and articles that may be made available as
separate IVD medical devices, they must comply with the content in sub-regulation (1) of
this regulation.

INSTRUCTIONS FOR USE FOR MEDICAL DEVICES

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

The instructions for use shall contain the following in at least English: and may be provided to the user in electronic
format; by way of exception, no such instructions for use are needed for devices in Class A or B if
they can be used safely without any such instructions:

Change in sub-regulation 31 (1) as Devices of class A or class B, and instruction for use may not
be applicable especially for grandfather products where the use is well understood in the market
and can be used safely and as intended by the manufacturer. In many cases due to the
complexity of the equipment or appliance the instructions may form part of an operating manual,
which may be electronic

(a) name or trade name of the medical device;
(b) name and business address of the legal manufacturer;
(c) where practical, the approved intended purpose for or use of the medical device or IVD
including in the case of a medical device, and where appropriate, the intended user;
(d) where the manufacturer has included clinical investigations as part of premarket
conformity assessment to demonstrate conformity to the safety and performance criteria, a
summary of the investigation, outcome data and clinical safety information, or a reference as to
where such information may be accessed;

Change in sub-regulation 31 (1) c for IVD exclusion as instructions for use are in regulation 32

(d) delete d) as this is included in the registration application documentation – clinical
investigations can differ between countries.
(e) any residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard;

Delete “any” because there are risks inherent with devices and “any” means ALL must be provided. In international practice users are informed of residual risks that are due to the shortcomings of the protection measures adopted e.g. “Contains Latex that may cause allergy”

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

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

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

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

(j) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
   (i) details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;
   (ii) identification of any consumable components and how to replace them;
   (iii) information on any necessary calibration to ensure that the device operates properly and safely during its intended life span; and
   (iv) methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing medical devices;

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

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

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

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

(o) for devices intended for use together with other medical devices and/or general purpose equipment:
   (i) information to identify such devices or equipment, in order to obtain a safe combination; and/or
   (ii) information on any known restrictions to combinations of medical devices and equipment;

(p) if the device emits hazardous, or potentially hazardous levels of radiation for medical purposes:
   (i) detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; and
   (ii) the means of protecting the patient, user, or third party from unintended radiation during use of the device;
(q) Information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device which information should cover, where appropriate:

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

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

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

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

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

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

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

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

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

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

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

Deletion in sub-regulation 31 (1) (s) of self-testing, inclusion of lay persons as defined in regulation 1.

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

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

Deletion in sub-regulation 31 (1) (u) as IVD is covered in Regulation 32 and to provide for technical machines refer regulation (j) (i)
INSTRUCTIONS FOR USE FOR IVDs

32 (1) Each package of a IVD shall have an instruction for use of the medical device that must contain the following information with regard to the medical device. The instructions for use shall contain the following in at least English, and may be provided to the user in electronic format.

Change in sub-regulation 32 (1) as in many cases due to the complexity of the equipment or appliance the instructions may form part of an operating manual, which may be electronic.

(a) the name or trade name;
(b) name and address of the manufacturer;
(c) the intended purpose/use, including but not limited to:
   (i) what is detected;
   (ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);
   (iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
   (iv) whether it is automated or not;
   (v) whether it is qualitative or quantitative;
   (vi) the type of specimen(s) required (e.g. serum, plasma, whole blood, tissue biopsy, urine); and
   (vii) testing population;
(d) an indication that it is for in vitro diagnostic use;
(e) the intended user as appropriate (e.g. layperson) an indication whether the device is intended for self-testing or near-patient testing;
(f) test principle;
(g) a description of the reagent, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);
   Note: IVD kits include individual reagents and articles that may be made available as separate IVDs. In this situation, where appropriate, these IVDs should comply with the instructions for use content in this section.
(h) a list of materials provided and a list of special materials required but not provided;
(i) for IVDs intended for use together with other IVDs or medical devices, and/or general purpose equipment:
   (i) information to identify such devices or equipment, in order to obtain a safe combination; and/or
   (ii) information on any known restrictions to combinations of medical devices and equipment;
(j) an indication of any special storage (e.g. temperature, light, humidity, etc.), storage and/or handling conditions that apply;
(k) in use stability which may include, the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;
(l) if the IVD is supplied as sterile, instructions in the event of the sterile packaging being damaged before use;
(m) information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the IVD which information should cover, where appropriate:
   (i) warnings, precautions and/or measures to be taken in the event of malfunction of the IVD or its degradation as suggested by changes in its appearance that may affect performance;
   (ii) warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
   (iii) warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g. electromagnetic interference emitted by the device affecting other equipment);
   (iv) precautions related to materials incorporated into the IVD that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction;
   (n) any warnings and/or precautions related to potentially infectious material that is included in the IVD;
   (o) where relevant, requirements for special facilities (e.g. clean room environment) or special training (e.g. radiation safety), or particular qualifications of the device user;
   (p) conditions for collection, handling, and preparation of the specimen;
   (q) details of any preparatory treatment or handling of the IVD before it is ready for use (e.g. reconstitution, calibration, etc.);
   (r) the information needed to verify whether the IVD is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:
      (i) details of the nature, and frequency, of preventative and regular maintenance (including cleaning and disinfection);
      (ii) identification of any consumable components and how to replace them;
      (iii) information on any necessary calibration to ensure that the IVD operates properly and safely during its intended life span;
      (iv) methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing IVD (e.g. contaminated surfaces);
   (s) where relevant, recommendations for quality control procedures;
   (t) the metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order;
   (u) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing should be considered;
   (v) analytical performance characteristics, such as sensitivity, specificity, and accuracy (which is a combination of trueness and precision);
   (w) where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity;
(x) where relevant, reference intervals;
(y) information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen/sample) that may affect the performance of the assay;
(z) warnings or precautions to be taken related to the disposal of the device, its accessories, and the consumables used with it, if any, which information should cover, where appropriate:
   (i) infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin);
   (ii) environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation); and
   (iii) physical hazards (e.g. explosion);
(aa) for IVDs intended for use by lay persons for the purpose of self-testing, the circumstances when the user should consult with a healthcare professional;

Addition in sub-regulation 32 aa) “for the purpose of self-testing as laypersons are not registered with a scope of practice with HPCSA

(bb) where relevant, a bibliography;
(cc) date of issue or latest revision of the instructions for use and, where appropriate, an identification number.
(dd) appropriate maintenance instructions for technical IVD machines, where applicable

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

Note: Definition was expanded so that these devices would not be required to go through the normal procedure for registering a device to be manufactured or imported. The physician prescribing use of the custom device in question would take all the responsibility for the health and safety of the patient.

USED OR REFURBISHED MEDICAL DEVICES
X.(1) a person selling a used or refurbished medical device or IVD shall
   i) provide the purchaser with the maintenance history of the medical device and
   ii) when required, perform all the tests required by the purchaser or the Council in order to ensure proper functioning of the device or IVD, or provide evidence of compliance according to the original manufacturer’s requirements.

Addition of a regulation for used or refurbished medical devices - it would be more appropriate to require the refurbishment to be in accordance with the manufacturer’s requirements.
RECORD OF IMPLANTABLE MEDICAL DEVICES AND CUSTOM MADE MEDICAL DEVICES

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

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

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

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

Edits in sub-regulation 34 (1) to match medical device traceability and practicality requirements, deletion of prescription as prescription pertains to medicines. Deletion of 34 (1) d as patient records would not be held by suppliers of medical devices due to confidentiality requirements. Deletion of sub-regulation 34 (1) h as this information would be found in the Technical Dossier of the medical device.

Deletion in sub-regulation 34 (2) as prescription pertains to medicines.

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

a. the date and transaction of every sale;
b. the proprietary name of the medical device;
c. the name and address of every purchaser;
d. the quantities sold; and
e. the batch number.

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

Deletion of sub-regulation 34 (3): duplication

TRANSITIONAL ARRANGEMENTS - UNLICENCED MANUFACTURERS, IMPORTERS, DISTRIBUTORS EXPORTERS AND WHOLESALERS

Transitional arrangements to include the requirement for consultation with industry to enable the regulator to understand the magnitude and capacity requirements for regulating medical devices and IVDs.
35 (1) Manufacturers, importers, exporters, distributors or wholesalers selling medical devices or IVDs in the Republic at the time of the commencement of these regulations shall, subject to regulation 8, be deemed to be trading legally.

Deletion in sub-regulation 35 (1) as exporters are excluded (as per regulation 8) and inclusion of distributor.

(2) All medical device and IVD establishments referred to in subsection (1) shall within a period determined by the Council, during the transitional period, be catalogued by company name, address, scope of activities and medical device and IVD fields

Addition of subregulation 35 (2) to enable the regulator to establish the scope of the medical device and IVD market and contributors and to separate organisations that are entering the market from pre-existing organisations.

(3) The Council shall issue notices in the Gazette calling for the licensing of manufacturers, importers, exporters distributors and wholesalers which notices will stipulate the conditions and time periods for licensing; and that during the process of licensing be deemed to be trading legally.

Delete exporters (per previous recommendation) and addition of distributors.

TRANSITIONAL ARRANGEMENTS - UNREGISTERED MEDICAL DEVICES AND IVDs

Transitional arrangements to include the requirement for consultation with industry to enable the regulator to understand the magnitude and capacity requirements for regulating medical devices and IVDs.

36 (1) Unregistered medical devices or IVDs sold or any other medical device or IVD introduced in the Republic at the time, or after the time, of the commencement of these regulations shall, subject to regulations 11, be deemed to be sold legally until such time as the call-up notice period, as issued in terms of section 14 (2) of the Act, for the medical device or IVDs has expired.

Addition in sub-regulation 36 (1) of unregistered medical devices or IVDs sold “or any other medical device or IVD introduced” in the Republic at the time or after the time of the commencement… to enable market access of new products not called up for registration.
(2) All medical device and IVDs referred to in subsection (1) shall within a period determined by the council, during the transitional period, be catalogued by:
   i. the brand name, where applicable the medical device or IVD and / or group or family;
   ii. product and / or group or family description
   iii. risk classification as per regulation 14
   iv. The company name as per regulation 35

Addition of sub-regulation 36 (2) to enable the regulator to establish the scope of the medical device and IVD market and products in market and to separate products that are entering the market from pre-existing medical devices and IVD. This will enable the regulator to plan an efficient and rational way of call up and to determine the regulatory burden they would face during each call up. Call up of sub-categories of classes should follow the classification rules.

(3) The Council shall issue notices from time to time in the Gazette calling for the registration of medical devices and IVDs which notices will stipulate which class, referred to in regulation 14, and product description, group and/or family of medical devices and IVDs, after consultation with industry, must be registered and providing the conditions and time periods for the application for registration.

Sub-regulation (3) to include product description, group and or family to enable a more definitive group or family of medical devices or IVDs, which will enable the regulator to plan an efficient and rational way of call up and to determine the regulatory burden.

Additions in sub- regulation 36 (3) to include the requirement for consultation with industry to enable the regulator to understand the magnitude of the administrative burden and capacity requirements.

(4) Notwithstanding sub-regulation 1 the Council may require any medical device or IVD to comply with any requirements that the Council may determine in order to ensure that the medical device or IVD is safe, of performance and of good quality; provided that during the process of registration the medical device or IVD can be traded legally.

Addition in sub-regulation 36 (4) the addition of “provided that during the process of registration the medical device or IVD can be traded legally” to enable the market to continue trading.

COMMENCEMENT

37. These Regulations are called Regulations relating to Medical Devices and In vitro Diagnostic Medical Devices (IVDs) made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) and will commence upon the date signed by the minister.
Note: Several requirements made in this document cannot be enforced without the publication by the authorities of implementation decrees outlining the specific measures and processes to be used. This would apply to all sections where the following statements amongst others appears” ….any other information as determined by the Council” or “ …as determined by the Council” or “ …as determined by the Council in accordance with the technical rules published in the Gazette”. Therefore the date of commencement of enforcement of these regulations cannot be upon the date signed by the Minister but shall be the date that these implementation decrees will be all available.