Medical Devices: Licensing and Compliance – Regulator Perspective

SAAPI

5 October 2017 - SAAPI Conference

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Contents / Agenda

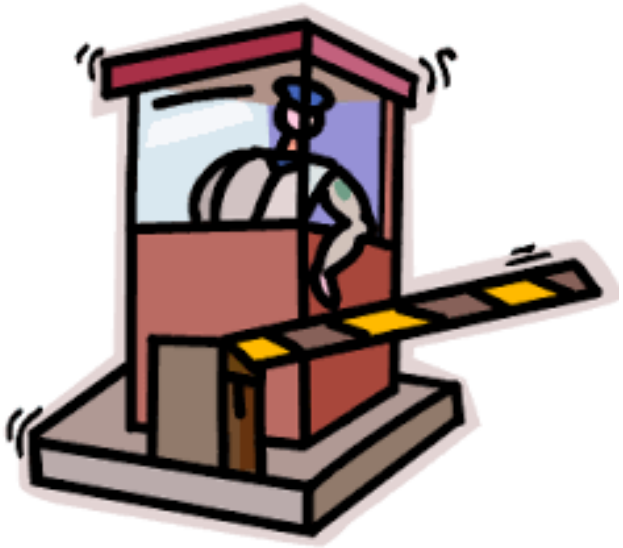
- Context
  - Role of Regulator
- Licensing [QMS and ISO 13485]
- Compliance

- Regulation and control of medicines and medical devices is not an option but an imperative for national health programs

- The challenge is to have the necessary policy objectives and the legislative provision and adequate and appropriate human, financial, technical and physical resources supported by appropriate SOPs and policy guidelines

The Regulator has two distinct objectives:

- Protect patients against harmful or ineffective medicines and medical devices
  - **Gatekeeper** function with obligation to apply stringent standards of assessment and to deny marketing authorization where deemed necessary



The Regulator has two distinct objectives:

- Protect patients against the consequences of untreated disease
  - **Enabling** medicine and medical device development to ensure that patients have access as early as possible to medicines and medical devices which are safe and perform as expected

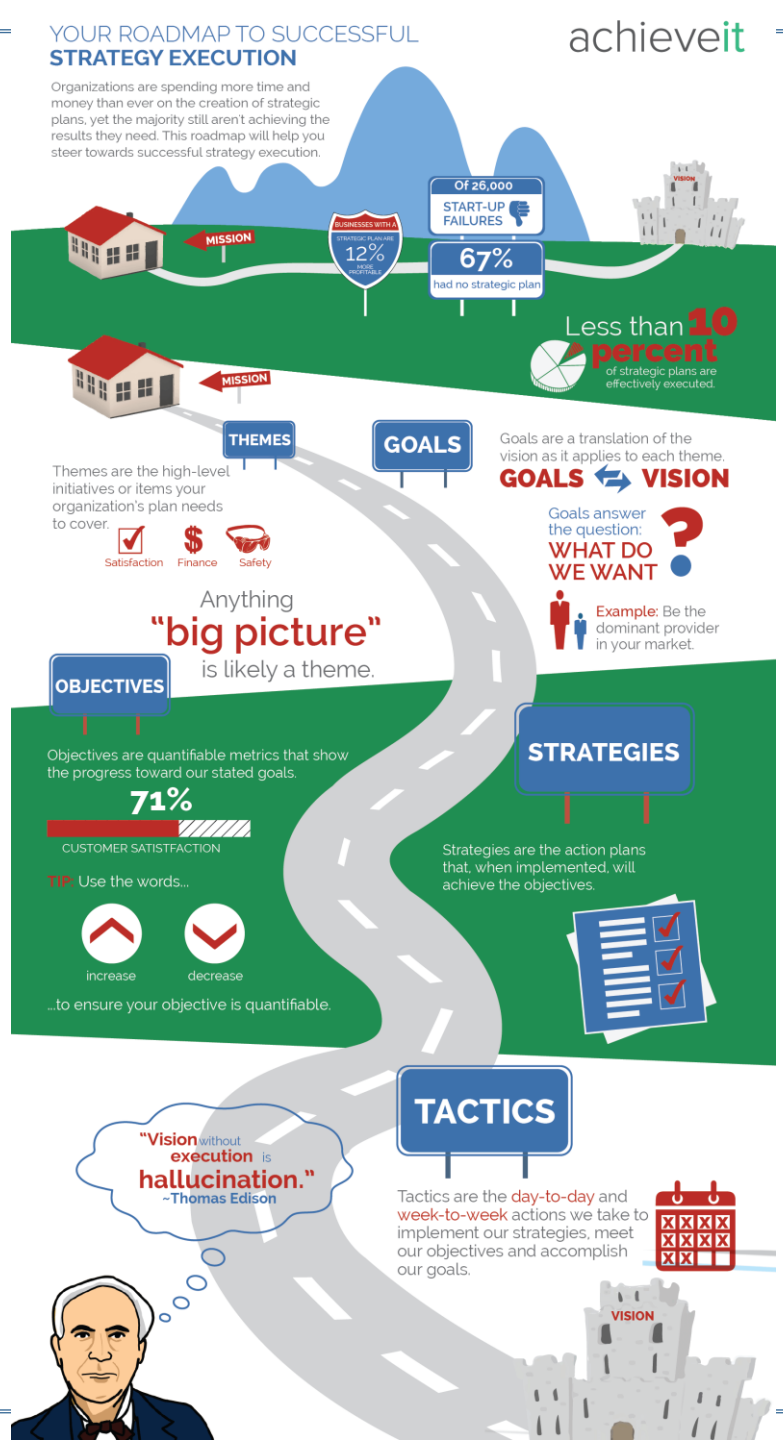
- National Health Policy (1996)
  - Adequate and reliable supply of safe, cost-effective medicines and devices of quality to all citizens
  - Rational use of medicines by prescribers, dispensers and consumers

- National Department of Health Strategic Plan

Legal Framework

- Medicines and Related Substances Act, 1965 (Act 101 of 1965)
  - Medicines Control Council
  - Registrar and Secretariat
  - Regulation and Control of Medicines (limited control over medical devices)
  - Licensing of Manufacturing, Storage and Distribution Facilities
- Act 72 of 2008: Establishing SAHPRA
- Act 14 of 2015: Transitional Arrangements MCC to SAHPRA
- Listing of SAHPRA as a 3A PE: 24 February 2017

SAHPRA will be responsible for:
monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest.


YOUR ROADMAP TO SUCCESSFUL
STRATEGY EXECUTION
achieveit
Organizations are spending more time and money than ever on the creation of strategic plans, yet the majority still aren't achieving the results they need. This roadmap will help you steer towards successful strategy execution.
MISSION
BUSINESSES WITH A STRATEGIC PLAN ARE 12% MORE PROFITABLE
Of 26,000 START-UP FAILURES
67% had no strategic plan
VISION
Less than 10 percent of strategic plans are effectively executed.
MISSION
THEMES
GOALS
Goals are a translation of the vision as it applies to each theme.
GOALS ⇄ VISION
Themes are the high-level initiatives or items your organization's plan needs to cover.
Satisfaction
Finance
Safety
Goals answer the question:
WHAT DO WE WANT
Example: Be the dominant provider in your market.
Anything "big picture" is likely a theme.
OBJECTIVES
Objectives are quantifiable metrics that show the progress toward our stated goals.
71%
CUSTOMER SATISTFACTION
TIP: Use the words...
increase
decrease
...to ensure your objective is quantifiable.
STRATEGIES
Strategies are the action plans that, when implemented, will achieve the objectives.
TACTICS
"Vision without execution is hallucination."
~Thomas Edison
Tactics are the day-to-day and week-to-week actions we take to implement our strategies, meet our objectives and accomplish our goals.
VISION


PLAN
DO
QUALITY
ACT

Essential Principles
of Safety and Performance

Other Published Standards

National & International Standards

.....

Scope specific

Conformity Assessment

Risk based Classification

Regulatory requirements

Essential Principles of Safety and Performance

Post Market surveillance

Two key requirements:

Quality Assurance

Act 101 "Regulatory Requirements"

- Medical device establishment
- Required for a licence to import/ manufacture/distribute/export
- Management responsibility
- Reference the "applicable regulatory requirements"
  - Act 101
  - OH&S
  - Hazardous Substances Act
  - Health Act
  - ICASA
  - POPI……..

1. License

of Medical device establishment

Listing of products imported/ manufactured
Minimum criteria for import
Class B, C & D

2. Registration

of Medical devices

Technical evidence to prove Essential principles of Safety & Performance are met

ISO 13485 "Quality Management System"

- Product safety & performance for users, patients & public health

Phased Implementation

Licence to a) manufacture; b) Import & distribute or c) Wholesale

Six months notice:

Authorised Representative

Quality Management System (declaration) ----> ISO13485 (2016)

Full list of Medical Devices by company & classification

Class C & D: Evidence of pre-market authorisation in either: “Originating approval”

USA (FDA);	EU (CE marking);	Japan;
Canada;	Australia;	Brazil
WHO Pre-Qualification IVD		

What will the Regulator Achieve in Phase 1a?

Licence to a) manufacture; b) Import & distribute or c) Wholesale

Six months notice:

Authorised Representative

Quality Management System (declaration) ----> ISO13485 (2016)

Full list of Medical Devices by company & classification

Class C & D: Evidence of pre-market authorisation in either: "Originating approval"

USA (FDA); EU (CE marking); Japan;
Canada; Australia; Brazil
WHO Pre-Qualification IVD

- Who is "in" the market?
- Who is the responsible person - Authorised Rep?
- What class of MDs does the Organisation import or manufacture?
- Nature of activities conducted in SA? Visibility of supply chain & stakeholders.
- Nature / status of QMS

Minimum standard for importation of Class C & D medical devices

Phase 1 Implementation

Licence to a) manufacture; b) Import & distribute or c) Wholesale

Six months notice:

Authorised Representative

Quality Management System (declaration) ----> ISO13485 (2016)

Full list of Medical Devices by company & classification

Class C & D: Evidence of pre-market authorisation in either: "Originating approval"

USA (FDA); EU (CE marking); Japan;
Canada; Australia; Brazil
WHO Pre-Qualification IVD

SANAS: Development of Conformity Assessment Framework for Medical Devices ISO 13485 (2016)

Accreditation of South African Conformity Assessment Bodies

What will be achieved in Phase 1b?

Licence to a) manufacture; b) Import & distribute or c) Wholesale

Six months notice:

Authorised Representative

Quality Management System (declaration) ----> ISO13485 (2016)

Full list of Medical Devices by company & classification

Class C & D: Evidence of pre-market authorisation in either: "Originating approval"

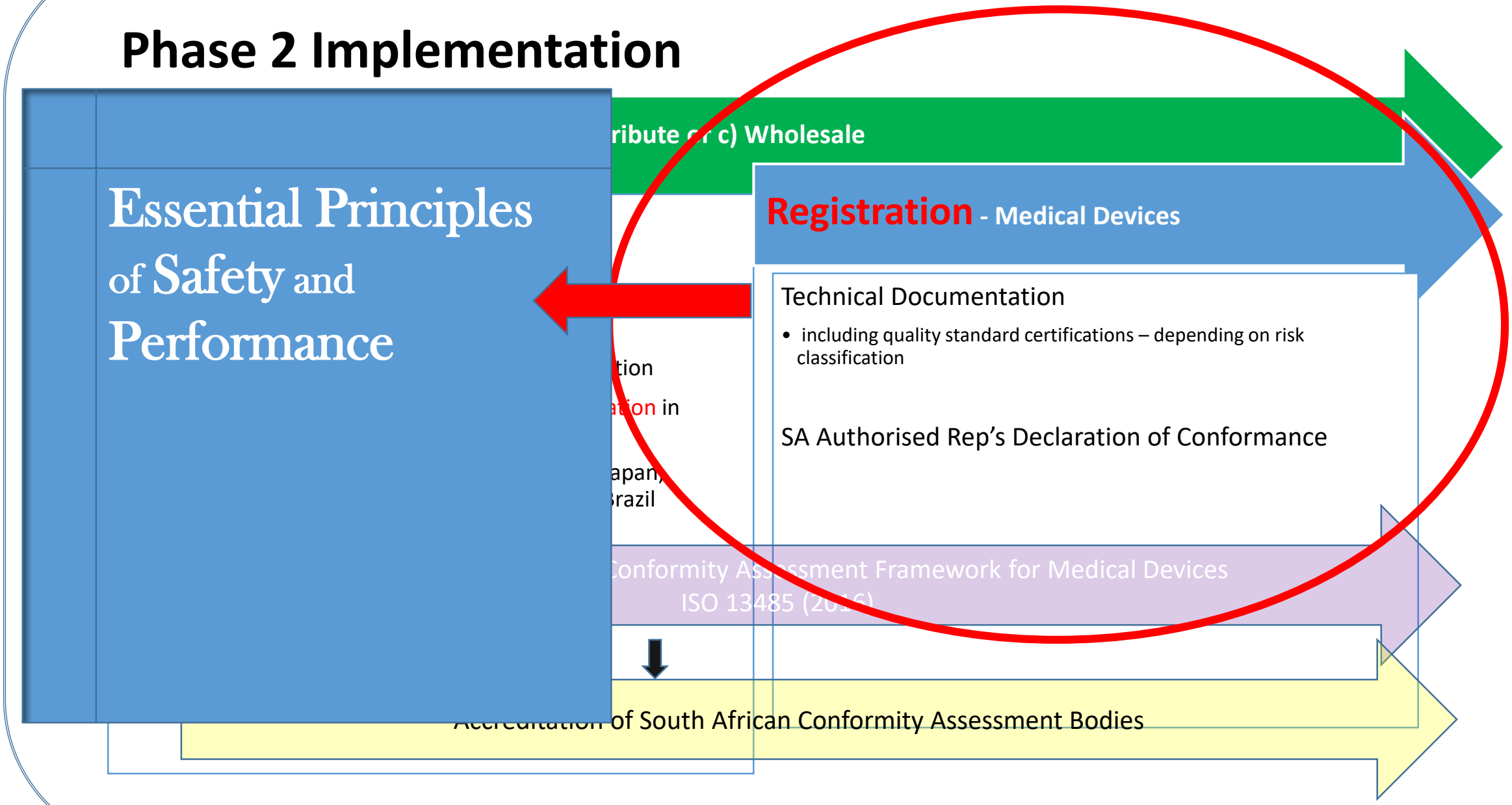
USA (FDA); EU (CE marking); Japan;
Canada; Australia; Brazil
WHO Pre-Qualification IVD

Establish Third party Conformity Assessment pathway

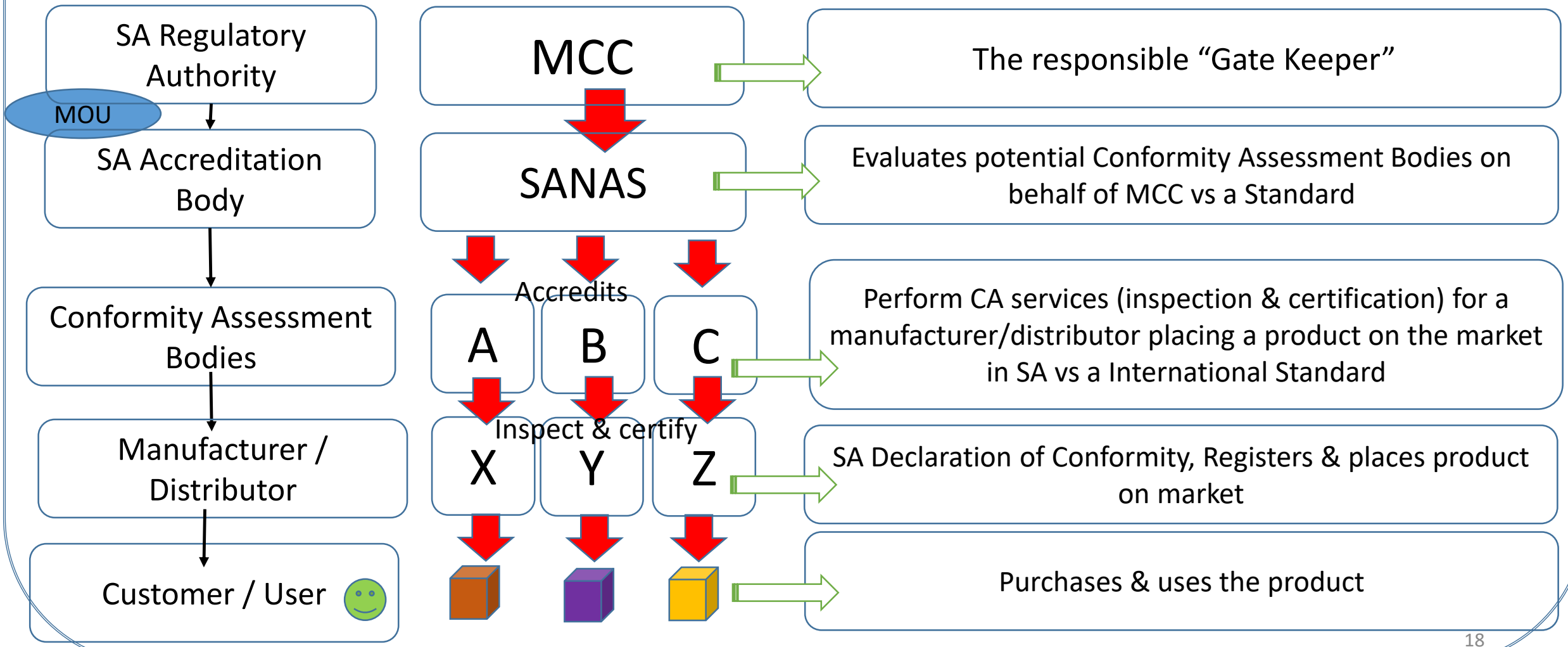
SANAS: Development of Conformity Assessment Framework for Medical Devices ISO 13485 (2016)

Accreditation of South African Conformity Assessment Bodies

Phase 2 Implementation



Conformity Assessment stakeholder relationships



Road Map

Medical Device Regulatory Road Map….2017

Final Regulations Medical Devices

Participate in Working Group

Quality manual guideline

2016

Jan

May

2017

Aug

GMDN registration

MD Committee established

Licensing Guideline

Training Secretariat Staff

Licensing Call-up Notice

Appoint Deputy Director Medical Devices

Medical Device Regulatory Road Map….2017

Process MD establishment Licence Applications

Establish database of Medical Devices & report on licensed medical device establishments

MCC appoint Designation Committee

2016

Jan

May

2017

Aug

Address MD licence establishment queries

Adverse Event & vigilance guideline

Publish DRAFT technical documentation for registration MD & guideline IVD and NON-IVD

Medical Device Regulatory Road Map….2017

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Publish DRAFT technical documentation for registration MD & guideline IVD and NON-IVD

MCC appoint Designation Committee

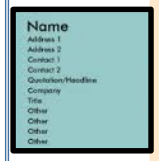
Reg 5. Licence to manufacture, import, export, or act as a distributor or wholesaler of medical devices or IVDs *cont.*

3 Types of licence:……..

(i) to **manufacture, import or export** medical devices or IVDs; or
(ii) to act as a **distributor**; or
(iii) to act as a **wholesaler** of medical devices or IVDs

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

Licensing Scenarios (1)



Activity	Type of Licence	Licensed to…
Import IVD / nIVD (finished product) AND Distribute finished products in SA ONLY	Import & Distribute Licence = Distributor Licence	Import, distribute, sell & make application to register a IVD/ nIVD
Import IVD / nIVD (finished product) AND distribute medical equipment in SA AND provide technical service	Import & Manufacture (Tech service) = Manufacturer Licence	Import, distribute, sell & provide technical service & make application to register a IVD/ nIVD
Import IVD / nIVD AND add a label (SA information) AND distribute medical equipment in SA	Import & Manufacture (Packing) = Manufacturer Licence	Import, label, distribute, sell & provide technical service & make application to register a IVD/ nIVD

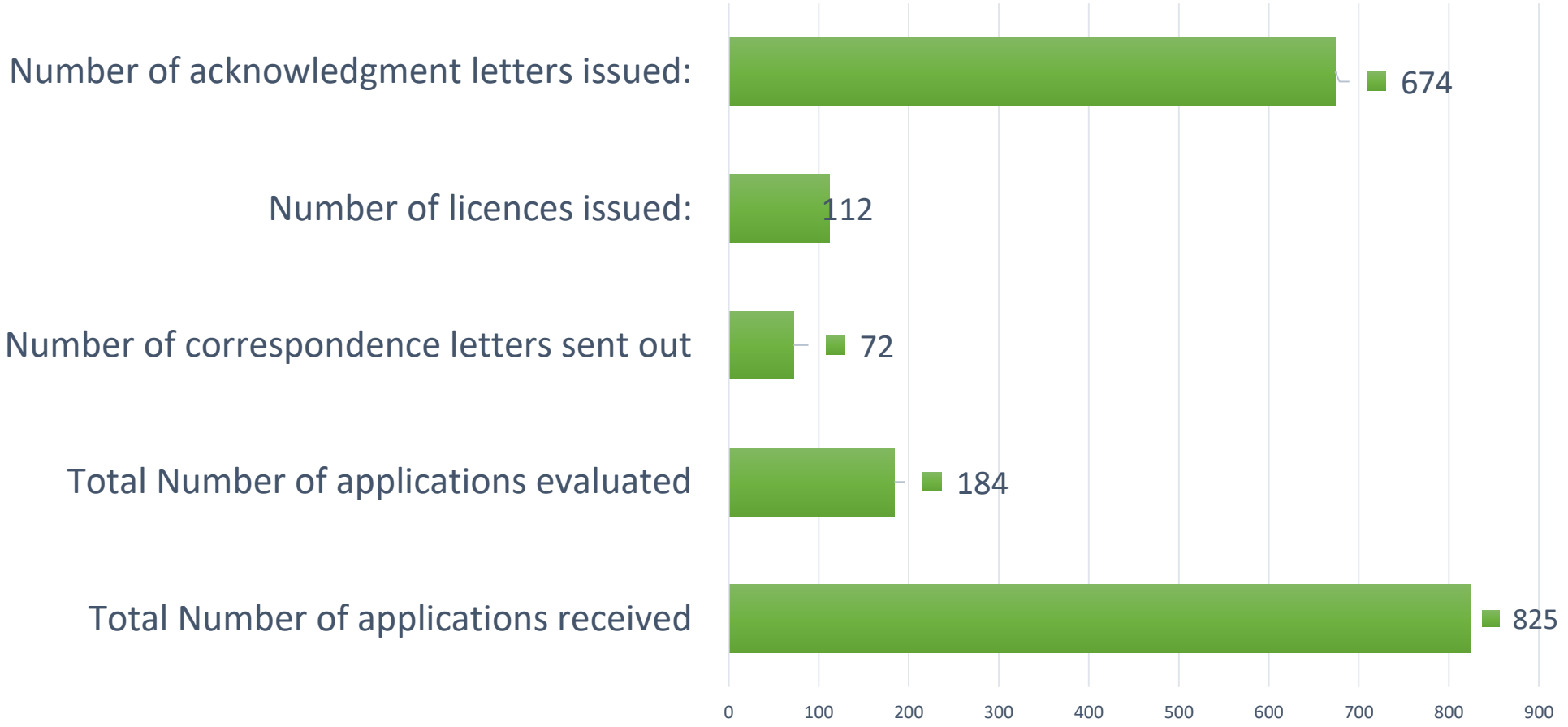
Licensing Scenarios (2)

Activity	Type of Licence	Licensed to…
i) Import & distribute IVD or nIVD (finished product) and ii) buy medical devices from another local company	i) Import & Distribute = Distributor Licence ii) Wholesaler Licence	i) Import, distribute, sell & make application to register a IVD/ nIVD ii) Wholesale
i) Import & distribute IVD or nIVD (finished product) and ii) Provide technical service iii) buy medical devices from another local company	i) Import & ii) Manufacture = Manufacture Licence iii) Wholesaler Licence	i) & ii) Import, distribute, sell & provide technical service & make application to register a IVD/ nIVD iii) Wholesale (different range of products)

Medical Device Establishment Licence Applications

Licence applications for medical devices

(12 September 2017):



Medical Device Wholesaler Licence Application

- By 23 February 2018

Two key requirements:

ISO 13485 "Quality Management System"

Act 101 "Regulatory Requirements"

- Medical device establishment
- Required for a licence to import/ manufacture/distribute/export
- Management responsibility
- Reference the "applicable regulatory requirements"
  - Act 101
  - OH&S
  - Hazardous Substances Act
  - Health Act
  - ICASA
  - POPI……..

1. License

of Medical device establishment

Listing of products imported/ manufactured
Minimum criteria for import
Class B, C & D
Good Wholesaling Practice

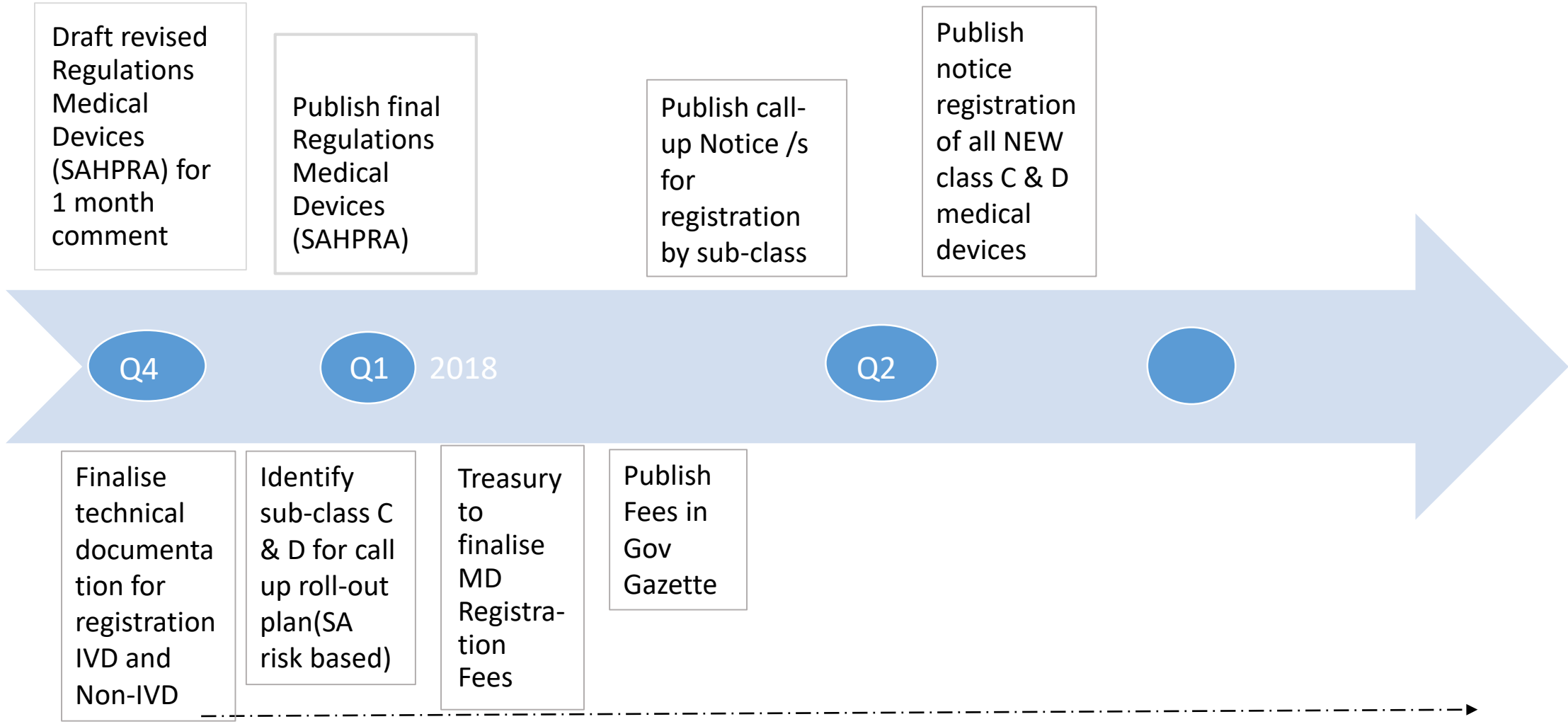
2. Registration

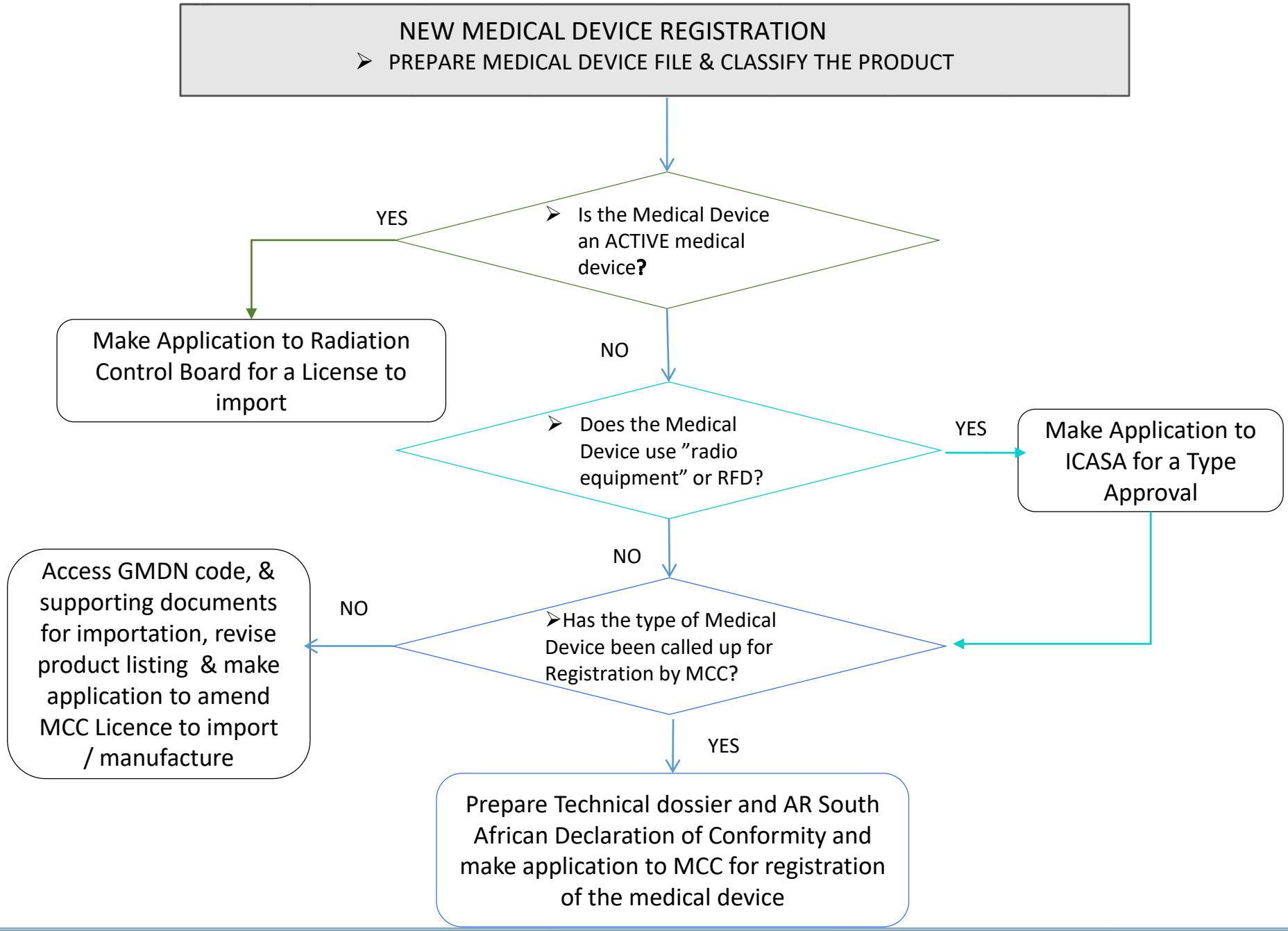
of Medical devices

Technical evidence to prove Essential principles of Safety & Performance are met

- Product safety & performance for users, patients & public health

Medical Device Regulatory Road Map....Q4 17 & 2018




NEW MEDICAL DEVICE REGISTRATION
PREPARE MEDICAL DEVICE FILE & CLASSIFY THE PRODUCT
Is the Medical Device an ACTIVE medical device?
YES
Make Application to Radiation Control Board for a License to import
NO
Does the Medical Device use "radio equipment" or RFD?
YES
Make Application to ICASA for a Type Approval
NO
Has the type of Medical Device been called up for Registration by MCC?
NO
Access GMDN code, & supporting documents for importation, revise product listing & make application to amend MCC Licence to import / manufacture
YES
Prepare Technical dossier and AR South African Declaration of Conformity and make application to MCC for registration of the medical device

Reg. 28 Transitional arrangements regarding unregistered medical devices & IVDs

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

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

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

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

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

Section 19. Prohibition on sale of medicine, medical devices or IVDs which do not comply with prescribed requirements and furnishing of information regarding medicines, medical devices of IVDs to the Authority

(1) No person shall sell any medicine, medical device or IVD unless it complies with the prescribed requirements.

Reg. 20 Compliance with requirements

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

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

(3) A proposed deviation from accepted s[illegible]ards and specifications referred to in sub regulations (1) and (2), must be submitted t[illegible]

NOTE:
Conformity to Essential Principles Safety & Performance; and
link to "originating approval" for Class C & D products.
Change control – refer Guideline

Reg. 17 Adverse event reporting & vigilance

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

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

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

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

Reg. 17 Adverse event reporting & vigilance cont.

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

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

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

(iii) any other data requested by the Council.

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

(3) Nothing in this regulation may be interpreted as prohibiting a person f… reporti… …rse event to the Council.

(4) Despite sub-regulation (1) or (3), a user who becomes aware of an adver… suspected of being caused by a medical device or IVD during the process of … marketing surveillance, must report the event either to the licensee, holde… registration, the manufacturer, the authorised representative or the Counc…

NOTE:
Implement & manage
Local complaint &
reporting system

GUIDELINE FOR RECALL, ADVERSE EVENT and POST-MARKETING VIGILANCE REPORTING of MEDICAL DEVICES and IVDs

- …to assist licensed manufacturers and distributors and HRC Medical Devices & IVDs in
  - the reporting of adverse events associated with the use of medical devices and IVDs;
  - the post-marketing vigilance for medical devices and IVDs; (this includes the management of safety data which arises during post-registration and post-marketing performance and clinical trials) and
  - the recall of a medical device or IVD from the marketplace.
- If there is a problem with a medical device or the way in which it is being used, the HRC & the licensed manufacturer or licensed distributor will first conduct an analysis and decide on the appropriate action. One of these actions may require notifying or obtaining further advice from the Council. Some actions that may need to be taken could include to:
  - follow corrective actions / preventive actions procedures under the manufacturer‘s / distributor’s quality management system,
  - inform the users of the device or IVD,
  - make corrections to the device or IVD,
  - remove, i.e. recall the medical device or IVD from the market.

GUIDELINE FOR RECALL, ADVERSE EVENT and POST-MARKETING VIGILANCE REPORTING of MEDICAL DEVICES and IVDs *cont.*

REPORTABLE ADVERSE EVENTS

- Any event that meets 3 basic reporting criteria, even if it does not involve a patient or user should be reported to the Council:
  - an adverse event has occurred
  - the licensed manufacturer's or licensed distributor's medical device is associated with the adverse event
  - the event led to or might lead to (often referred to as a near adverse event) death or serious injury, or might lead to death or serious injury if it were to occur again.
- An adverse event is an event that may lead to:
  - death, or
  - a serious injury or serious deterioration to a patient, user or other person, including
    - a life-threatening illness or injury
    - permanent impairment of a body function
    - permanent damage to a body structure
    - a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
- A 'near adverse event' is an event that might have led to a death or serious injury. It may be that due to the timely intervention of a healthcare practitioner a death or serious injury did not occur. For an event to be defined as a near adverse event, it is sufficient that:
  - an event associated with the device happened
  - if the event occurred again, it might lead to death or serious injury
  - testing or examination of the device or the information supplied with the device, or scientific literature indicated some factor that could lead to a death or serious injury.

GUIDELINE FOR RECALL, ADVERSE EVENT and POST-MARKETING VIGILANCE REPORTING of MEDICAL DEVICES and IVDs *cont.*

EXEMPTIONS FROM REPORTING ADVERSE EVENTS TO THE COUNCIL

- There are eight exemption rules that can apply (see table of exemption rules overleaf). However, these rules do NOT apply when:
    - a device, event or issue specifically identified by the Council as an issue that requires close monitoring—applicants of devices that are affected will be notified by the Council when this occurs
    - an adverse event normally subject to a reporting exemption, where a change in trend (usually an increase in frequency) or pattern is identified
    - adverse events associated with user error, as the Council may use this data to identify trends with similar products that may lead to recommendations for:
        - corrective action for the device
        - revising the labelling or *Instructions for Use*
        - identifying a need for increased user education.

If a manufacturer believes an exemption rule applies to reporting an adverse event, the reasons for not reporting the event should be documented.

EXEMPTION RULES FROM REPORTING ADVERSE EVENTS TO THE COUNCIL

Rule No	Exemption Rules
1	Deficiency of a new device found by the user prior to its use
2	Adverse event caused solely by patient conditions
3	Service life of the medical device The service life is defined as '*the time or usage that a device is intended to remain functional after it is manufactured, placed into use, and maintained as specified*'. The service life must be specified by the device manufacturer and included in the master record (technical file).
4	Protection against a fault functioned correctly
5	Remote likelihood of occurrence of death or serious injury
6	Expected and foreseeable side effects that are documented in manufacturer's Instructions for Use or labelling
7	Adverse events described in an advisory notice
8	Reporting exemptions granted by the Council

5.4 TIME FRAMES FOR SUBMITTING ADVERSE EVENTS REPORTS TO COUNCIL

HRC must give information to the Council is:

5.4.1 if the event …… serious threat to public health-48 hours after the person becomes aware of the event or occurrence; **and**

5.4.2 if the event…… led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person-10 calendar days after the person becomes aware of the event or occurrence; **and**

5.4.3 if the event……..which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person-30 days after the person becomes aware of the event or occurrence.

QUALITY DEFECTS OF MEDICAL DEVICES AND IVDS

If the HRC or licensed manufacturer or licensed distributor is contemplating any of the following:

- correcting product on the market
- removing product from the market, or
- advising users of an issue with a medical device

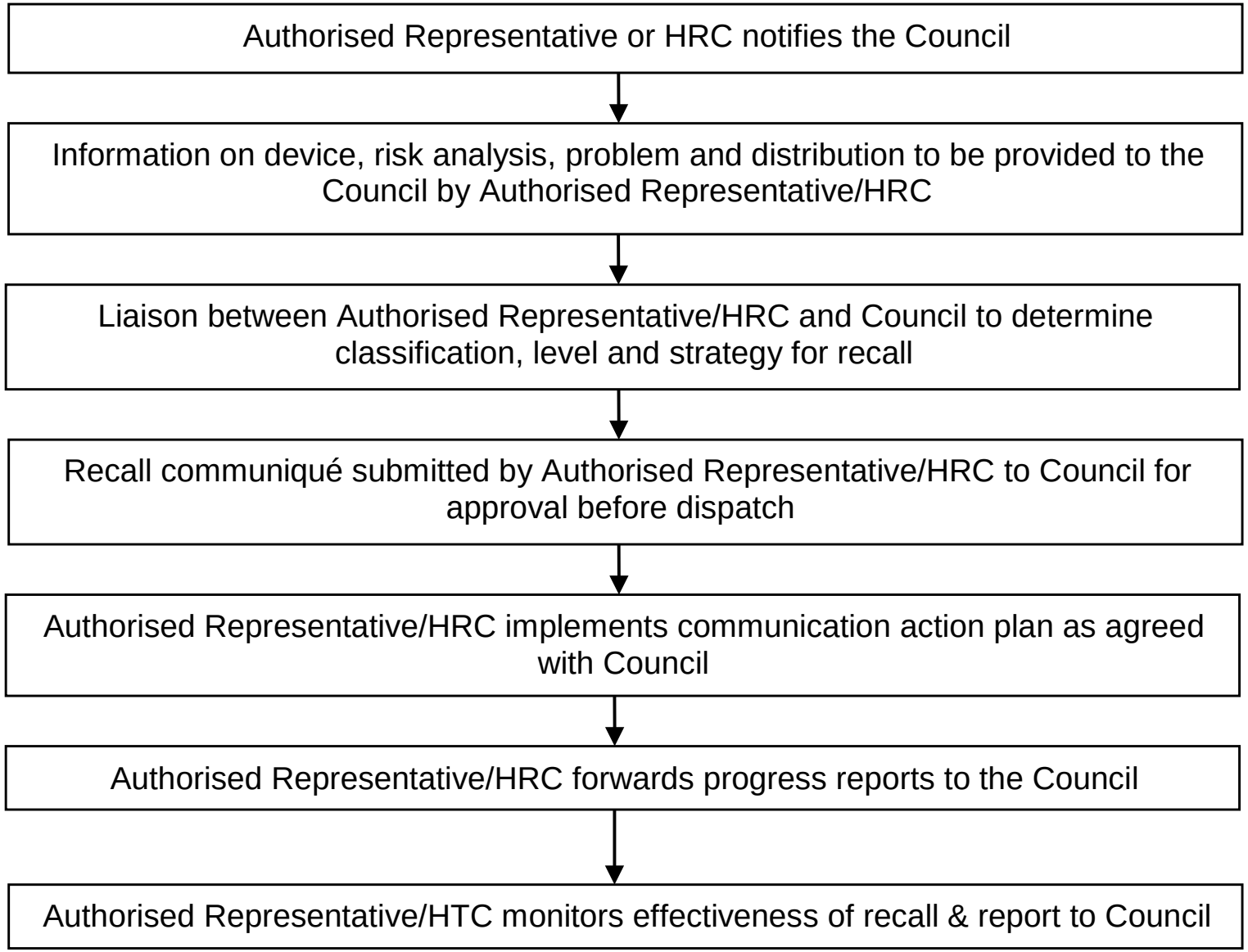
contact the Vigilance Unit at the office of the Registrar for advice.

When the need for a recall of a medical device supplied in or exported from South Africa has been established, the HRC or licensed manufacturer or licensed distributor of the affected device is responsible for the recovery of the devices.

NON RECALL ACTIONS FOR MEDICAL DEVICE / IVD

Action	Description
Safety Alert	Intended to provide information on safe use of devices, as distinct from recall action, which addresses product deficiencies Issued to provide additional advice to health professionals in situations where the device, although meeting all specifications and therapeutic indications, its use could present an unreasonable risk of substantial harm if certain specified precautions or advice are not observed. For example, specific precautions about the longevity of an implanted medical device
Product Notification	Issue of precautionary information about a device in a situation that is unlikely to involve significant adverse health consequences
Product Withdrawal	HRC's removal from supply or use of devices for reasons not related to their quality, safety or performance
Product Recovery	The HRC recovers devices that have been manufactured or imported but not yet supplied to the market. For example, recovery of devices in a warehouse
User information	Generally conducted by the HRC in response to issues with the use of a medical device or IVD Includes in-house sessions, seminars and improved educational materials such as posters

STAGES OF A RECALL



10. CLASSIFICATION OF RECALLS

- Recalls are classified into both the
  - **class** according to the level of health hazard involved (risk to the patient, user or public health) **and**
  - **type** which denotes the depth or extent to which the product should be recalled from the distribution chain, e.g. Class I, Type C recall, etc.
- Class I or Class II recalls are considered to be urgent safety-related recalls.
- Class III recalls are considered to be routine non safety-related recalls

10. CLASSIFICATION OF RECALLS *CONT.*

Classification	Description	Examples relating to Medical Devices
Class I (Safety related)	Product defects are defective/dangerous/ potentially life-threatening that predictably or probably could result in serious health risk/adverse events or even death and could cause permanent debilitating health issues.	Hot/cold gel packs that contain a toxic substance that could be ingested accidentally by a young child A software error in a CT scanner that could cause the gantry to rotate in an unintended direction and cause an injury to or the death of a patient Implantable pacemakers with a defect that results in a loss of pacing output, which for pacemaker-dependent patients may result in death or serious injury A false result on an IVD test for a medicine with a narrow therapeutic index that could lead to an overdose, causing permanent injury
Class II (Safety related)	Product defects could cause illness, temporary or medically reversible adverse health problem or mistreatment and the recovery of the patient is likely	Microbial contamination of a surgical lubricant A software error in a radiation treatment planning tool that could lead to therapy being miscalculated and incorrectly administered The *Instructions for Use* for a catheter omits a precaution for certain procedures that could cause complications in its removal The incorrect combination of metal femoral heads and liners has been supplied to surgeons. If implanted then there is a high risk of accelerated wear and tear An IVD test kit that could identify the wrong strain of micro- organism and lead to inappropriate treatment

10. CLASSIFICATION OF RECALLS *CONT.*

Classification	Description	Examples relating to Medical Devices
Class III (Non-Safety related)	Product defects may not pose a significant hazard to health, but are defective and are unlikely to cause any adverse health reaction, withdrawal may be initiated for other reasons, or which do not comply with the requirements of Act 101 of 1965 in terms of the requirements of printed packaging material, product specification, labeling, etc.	A disinfectant has been mislabelled with an expiry date that predates the actual expiry date. The outer packaging of a consumable medical device indicates a different size to that which is actually in the supplied in the box. It would be obvious to the clinician that the consumable was the incorrect size An IVD reagent is causing calibration failures towards the end of its shelf life. There is no effect on patient results

Labelling & advertising

Act 101 Definitions

'label', when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun, means any brand or mark or any written, pictorial or other descriptive matter appearing on or attached to or packed with and referring to any article or the package containing any article;

'**advertisement**', in relation to any medicine, Scheduled substance**,** medical device or IVD, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

(a) appearing in any newspaper, magazine, pamphlet, electronic media (including radio and television) or other publication;

(b) distributed to members of the public; or

(c) brought to the notice of members of the public in any manner whatsoever,

which is intended to promote the sale of that medicine, Scheduled substance, medical device or IVD, and 'advertise' has a corresponding meaning;

Section 18. Labels and advertisements

(1) No person shall sell any

(a) medicine or Scheduled substance unless the immediate container or the package in which that medicine or Scheduled substance is sold bears a label stating the prescribed particulars.

(b) medical device or IVD unless the medical device or IVD, or its packaging, bears a label, where practical stating the prescribed particulars and

(2) No person shall advertise any medicine or Scheduled substance, medical device or IVD for sale unless such advertisement complies with the prescribed requirements.

(3) The label referred to in subsection (1) shall be approved by the Authority.

(4) The Authority may authorize a deviation from the prescribed format and contents of any label.

(5) The Minister may prescribe additional requirements for the labeling of medicines, Scheduled substances, medical devices or IVDs.

Reg. 22. Labelling of medical device or IVDs

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

(a)	The name or trade name of the medical device or IVD;	
(b)	product description and intended use;	
(c)	a product catalogue code, where applicable;	
(d)	the name and business address of the manufacturer;	
(e)	the name and business address of the holder of the certificate of registration;	
(f)	where appropriate, an indication that the medical device contains or incorporates a scheduled or biological substance;	
(g)	the lot number, where applicable;	
(h)	the serial number, where applicable;	
(i)	for accessories, the serial number may be substituted with a control number and for software it may be substituted with a version number;	

Reg. 22. Labelling of medical device or IVDs (cont.)

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

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

(b) on the packaging of each unit; and

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

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

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

Reg 21. Advertising of medical devices or IVDs

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

(a) Only Class A and Class B medical devices and IVDs
person.

(b) despite sub-regulation (a), male or female condoms ma

(c) an advertisement for a medical device or IVD may not
is in conflict with or goes beyond, the evidence submitte
medical device or IVD with regard to its safety, quality, o
been-

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

(ii) incorporated into the approved instructions for use of the medica

NOTE:
Class C and D may NOT be advertised to the public.
All promotional activities to be reviewed.
Only advertise to health professionals

Reg 21. Advertising of medical devices or IVDs cont.

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

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

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

(e) (i) when a Class C or Class D medical device or IVD is advertise
user, written information, which must include at least the informati
regulation 24 as the case may be, must simultaneously be given to th
electronic or printed advertisement is directed; and

(ii) when the medical device or IVD is advertised on subsequent occa
available on request.

NOTE:
INFORMATION WHICH MUST BE INCLUDED WHEN FIRST ADVERTISED & AVAILABLE AT LAUNCH

Instructions for Use

Reg. 23. Instruction for use medical device

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

(a)	The name or trade name of the medical device;	
(b)	the name and business address of the manufacturer;	
(c)	where practical, the approved intended purpose or use of the medical device and where appropriate, the intended user;	
(d)	residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard;	
(e)	specifications that the user requires in order to use the medical device appropriately (e.g. if the device has a measuring function, the degree of accuracy claimed for it);	
(f)	if the medical device contains, or incorporates, a scheduled substance or a biological substance, identification of that substance, as appropriate;	
(g)	details of any preparatory treatment or handling of the medical device before it is ready for use (e.g. sterilisation, final assembly, calibration, etc.);	
(h)	any requirements for special facilities, or special training, or particular qualifications of the medical device user or third parties;	

Reg. 23. Instruction for Use medical device cont.

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

Reg 24. Instruction for use IVD

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

(a)	The name or trade name of the medical device;	
(b)	the name and business address of the manufacturer;	
(c)	the intended purpose and use, including but not limited to	
(i)	what is detected;	
(ii)	its function;	
(iii)	the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;	
(iv)	whether it is automated or not;	
(v)	whether it is qualitative or quantitative;	
(vi)	The type of specimens required (e.g. serum, plasma, whole blood, tissue biopsy, urine); and;	
(vii)	testing population;	

Reg 24. Instruction for use IVD - cont.

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

(aa)	warnings or precautions to be taken related to the disposal of the medical device, its accessories, and the consumables used with it, if any, which information must cover, where appropriate--
(i)	infection or microbial hazards;
(ii)	environmental hazards; and
(iii)	physical hazards;
(bb)	for an IVD intended for use by a lay person, the circumstances when the user must consult with a healthcare professional;
(cc)	where relevant, a bibliography;
(dd)	the date of issue or latest revision of the instructions for use and, where appropriate, an identification number; and
(ee)	appropriate maintenance instructions for technical IVD machines, where applicable

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

Q&A

Thank you!

Regulations for medical devices & IVDs

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

Regulations for medical devices & IVDs- cont.

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

Key definitions

‘**medical device**’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) —

intended by the manufacturer to be used, alone or in combination, for humans or animals for one or more of the following:

diagnosis, prevention, monitoring, treatment or alleviation of disease;

diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement, modification, or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes bemeans of *in vitro* examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;

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

‘**medical device or IVD establishment**’ means a facility used by a manufacturer, wholesaler, distributor retailer, service provider or an importer of medical devices or IVDs for conducting business;

'sell' means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and 'sale' and 'sold' have corresponding meanings;

‘vigilance’ in relation to a medicine, medical device or IVD, means the continuous monitoring and evaluation of its safety, efficacy and performance profile and the management of any risk throughout its life-cycle.’’.

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

"manufacturer" means -

(a) a natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD before it is placed on the market under the natural or legal person's own name, or in the name of a firm or company, regardless of whether these operations are carried out by that person by himself or on his or her behalf by a third party; or

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

“distributor” means a natural or legal person who-

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

(b) sells the medical device or IVD to a healthcare professional, healthcare institution, wholesaler or the user;

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