UPDATE: Regulatory Framework for Medical Devices in South Africa

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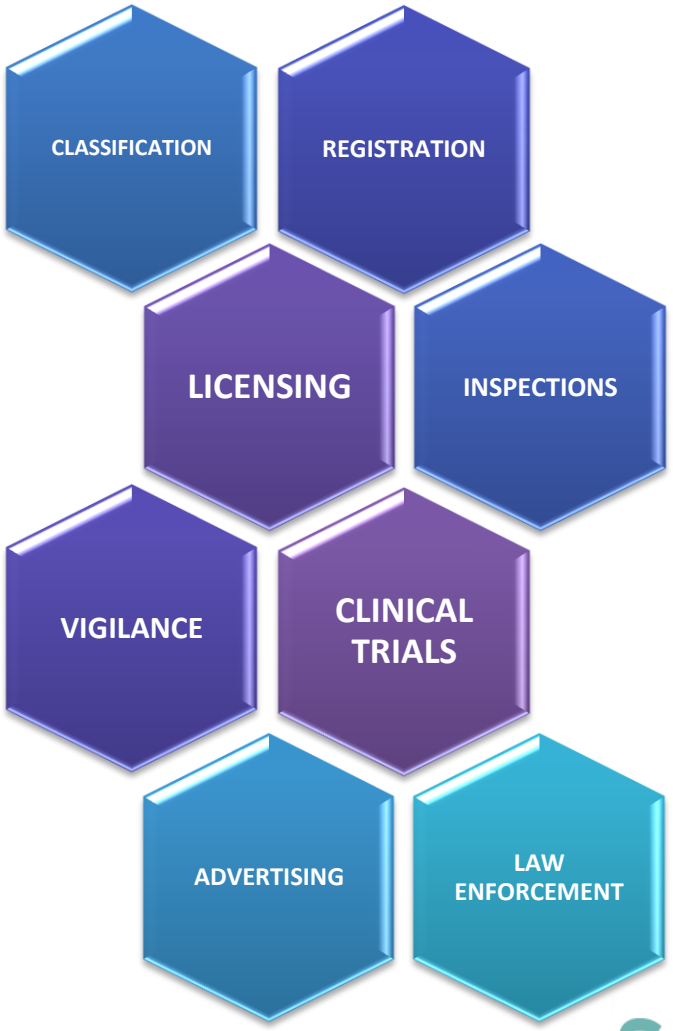
health
Department:
Health
REPUBLIC OF SOUTH AFRICA

SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

South African Regulatory Road Map - Phased Implementation



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South African Regulatory Road Map - Phased Implementation

- **REGISTRATION**
  - Call-up Plan (to be published in Q4 2018)
  - Fees (to be published in Q4 2018)

- **Request For Designation**
  - Procedure described in Section 7 of Borderline Guideline
  - Applications may be submitted to Medical Device Unit
  - Applications will be considered by Designation Committee

- **Application forms & Guidelines for registration**
  - To be published for implementation in Q4 2018
  - **ZACH1.04 / MDTD01 / MDTD02 / 8.08 / 8.09**

South African Regulatory Road Map - Phased Implementation

- **LICENSING**
  - Manufacturers & Distributors (Call up: Deadline - 24/08/2017)
  - Wholesalers (Call up: Deadline - 24/02/2018)
  - Licence valid for 5 years

- **Application Forms (available on the website)**
  - **6.21** Licence Application: Manufacturer
  - **6.22** Licence Application: Distributor
  - **6.26** Licence Application: Wholesaler

- **Fees**
  - Manufacturer – R 21 800
  - Distributor – R 13 000
  - Wholesaler – R 13 000
  - RETENTION FEE – R 3 000

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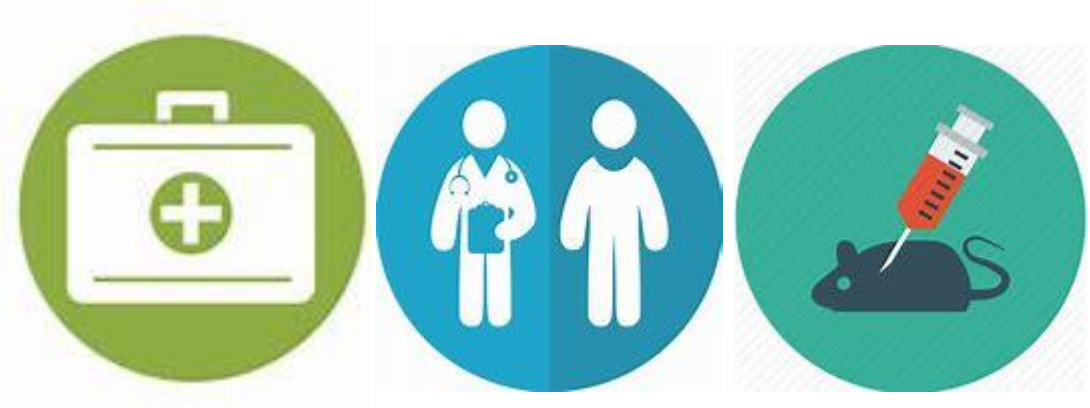
- **CLINICAL TRIALS**
  - As of 1 June 2017 all protocols for clinical trials with medical devices must be approved by SAHPRA prior to initiation of the trial
  - Use the CTF 1 Form to apply to SAHPRA
  - All applications are evaluated by the Clinical Trial Committee and the Medical Device Committee



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Regulation 21: ADVERTISING

- Only Class A and Class B medical devices and IVDs may be advertised to the public or a lay person.
- Male or female condoms (Class C) may be advertised to the public.
- A written advertisement for a medical device or IVD must contain:
  - the name of the medical device or IVD; and
  - in the case of a registered medical device or IVD, the registration number allocated to the medical device

South African Regulatory Road Map - Phased Implementation

- **INSPECTIONS**
  - Manufacturers & Distributors
    - Inspected by Conformity Assessment Bodies
    - Must be certified against ISO 13485
  - Wholesalers
    - Inspected by SAHPRA Inspectorate
    - Must have a positive Good Wholesaling Practice status
  - Upon application for licence renewal (in 5 years)
    - Licence holders must provide evidence of ISO 13485 certification / positive GWP status
    - Licence will not be renewed without this evidence being provided

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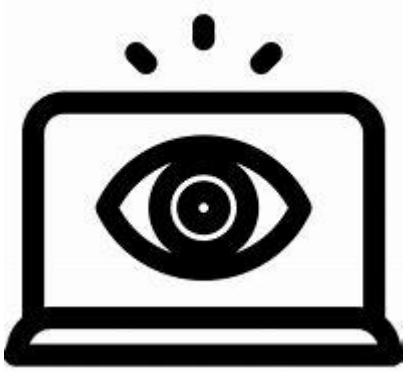


- **VIGILANCE**
  - **Vigilance requirements are in force**
  - **Guideline**
    - **8.04** Guideline for Recall, Adverse Event and Post-Marketing Vigilance Reporting of Medical Devices and IVDs
    - Planned improvements to guideline – application form will be published for comment in Q4 2018

Authorised Representative

"authorised representative" means a 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;
- **acts on behalf** of a manufacturer, importer, distributor, wholesaler, retailer or service provider for specified tasks with regard to the latter's obligations and in whose name the manufacturer licence, distributor licence, wholesaler licence or certificate of registration is issued; and
- is **responsible** for all aspects of the medical device or IVD, including performance, quality, safety and compliance with conditions of registration, clinical trials or clinical investigations.

Regulation 5: Licensing

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

- appoint and designate an authorised representative who must reside in South Africa-
  - be responsible to the Authority for compliance with the Act; and
  - control the manufacturing, distribution, wholesaling and the sale of medical devices or IVDs.

Regulation 5: Licensing

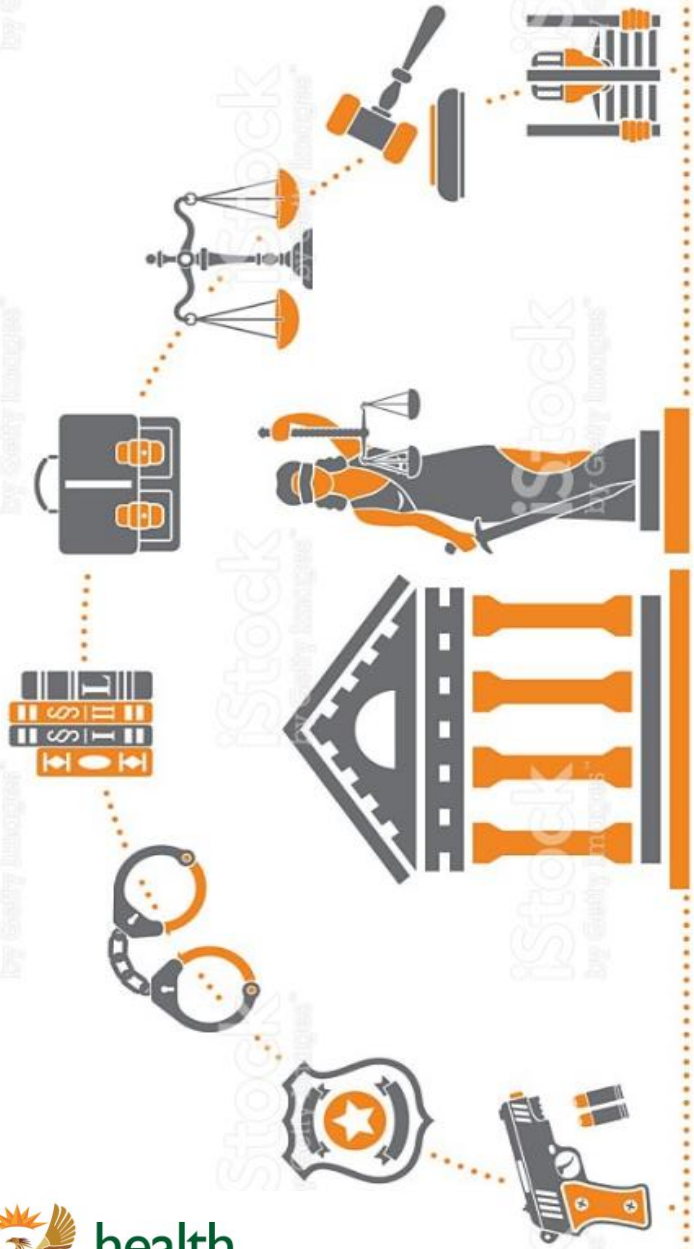
- The Authority may, subject to sub-regulation (11), direct the CEO to remove the name of a licensee from the register if the authorised representative fails to control the manufacturing or distribution, wholesaling or sale of the medical devices *or* IVDs

Regulation 8: Registration

- An application for registration of a medical device or IVD must be accompanied by a **declaration of conformity** by the authorised representative as determined by the Authority
- A **declaration** by the authorised representative that the information furnished is **complete and accurate**

Regulation 17 : Adverse Event Reporting

- An authorised representative must inform the Authority, in the manner and within the time frame determined by the Authority, of a suspected adverse event, reported to him or her, occurring as a result of the use of the medical device or IVD.



Regulation 19: Offences and Penalties

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

- Regulations 3 or 4 with regard to the importation or transmission of medical devices;
- Regulation 5 with regard to the licence to manufacture, act as a distributor or act as a wholesaler of medical devices;
- Regulation 14 with regard to the destruction of medical devices;
- Regulation 16 with regard to the conduct of clinical trials;
- Regulation 21 with regard to the advertising of medical devices;
- Regulation 22 with regard to the labelling of medical devices;
- Regulation 23 with regard to the instructions for the use of a medical device;
- Regulation 24 with regard to the instructions for use of an IVD;
- Regulation 20 with regard to the compliance to the Essential Principles confirmed in the declaration of conformity; or
- Regulation 17 with regard to reporting of adverse events and vigilance,

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

Guideline For Recall, Adverse Event And Post-marketing Vigilance Reporting of Medical Devices

Problem with a medical device or the way in which it is being used:

- HCR & the licensed manufacturer/distributor will
  - Conduct an analysis and decide on the appropriate action (One of these actions may require notifying or obtaining further advice from the Authority).
  - Some actions that may need to be taken could include to:
    - follow corrective actions / preventive actions procedures under 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 from market

Reportable Adverse Events

- A 'near adverse event' is an event that might have led to a death or serious injury
- 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

Reportable Adverse Events

An adverse event is an event that may lead to:

- death, or
- a serious injury
- 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
  - permanent damage to a body structure

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 Authority:

- An adverse event has occurred
- The licensed manufacturer's/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.

Exemptions From Reporting Adverse Events To The Authority

There are eight exemption rules that can apply

However, these rules do **NOT apply** when:

- A device, event or issue specifically identified by the Authority as an issue that requires close monitoring —applicants of devices that are affected will be notified by the Authority 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 Authority 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

Rule No	
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 Authority

Timelines for Reporting

- If the event …… **serious threat to public health**
  - **48 hours** after the person becomes aware of the event or occurrence; **and**
- If the event…… **led to the death, or a serious deterioration in the state of health**
  - **10 calendar days** after the person becomes aware of the event or occurrence; **and**
- If the event……**which might lead to the death, or a serious deterioration in the state of health**
  - **30 days** after the person becomes aware of the event or occurrence

To Recall or Not?

If the HCR or licensed manufacturer / 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 Medical Device Unit

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

Non-Recall Actions for Medical Devices

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

Classification of Recalls

NOTE:

Decisions on the Class and Type of a recall to be initiated are a matter of the Authority in consultation with a HCR/licensed manufacturer/licensed distributor and shall be based on the evidence and/or expert opinion of the Authority and HCR.

Recalls

Recalls are classified by:

- **CLASS** according to the level of health hazard involved (risk to the patient, user or public health) **and**
  - 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
- **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.
  - Type A / Type B / Type C

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Thank You