Regulatory Framework for Medical Devices in South Africa

23 November 2018

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Deputy Director: Medical Devices

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

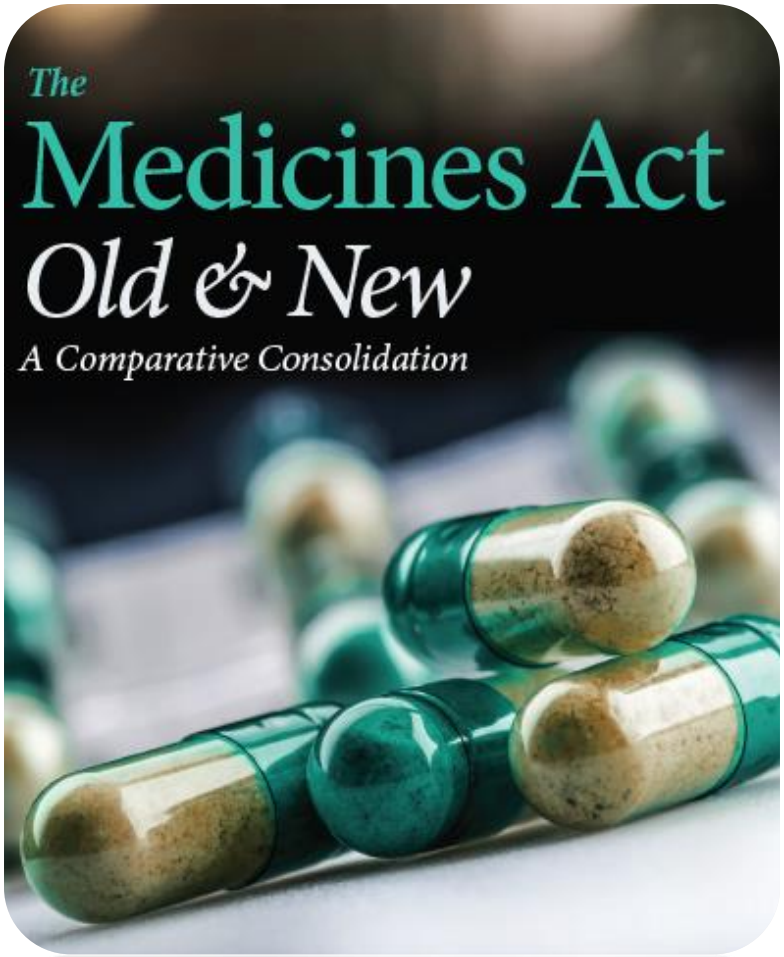
Medicines and Related Substances Act, 1965 (Act 101 of 1965)

Act 72 of 2008 and Act 14 of 2015

- Provides for the establishment of a new regulatory authority (SAHPRA)
- Provides for transition of MCC to SAHPRA
- Provides for expansion of the regulatory mandate of the Authority to include the regulatory oversight of Medical Devices
- Promulgation: June 2017

Regulations for Medical Devices & IVDs:

- Publication 9 December 2016, Government Gazette No 40480, No 1515



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Regulations for Medical Devices

SUPPLY OF MEDICAL DEVICES

1. Definitions
2. Manner and conditions for allowing international tendering
3. Importation of medical devices into Republic
4. Transmission of medical devices through Republic

REGISTRATION OF MEDICAL DEVICES

5. **Classification of medical devices**
6. Labelling of medical devices
7. Instructions for use of a medical device which is not an IVD
8. Instructions for use of an IVD
9. **Application for registration of a medical device**
10. Information that must appear in register for medical devices
11. Application for amendment to register for medical devices
12. Certificate of registration

PERMITS, LICENSING AND AUTHORISATION

13. **Licence to manufacture, distribute or wholesale medical devices**
14. Period of validity and renewal of licence issued in terms of regulation 13

Regulations for Medical Devices

MANAGEMENT OF MEDICAL DEVICES

15. Parts and components
16. Destruction of medical devices
17. **Conduct of clinical trial of medical devices**
18. **Adverse event reporting and vigilance for medical devices**
19. Custom made medical devices
20. Record of implantable medical devices and custom made medical devices
21. **Advertising of medical devices**
22. Appraisal and exhibition of medical devices

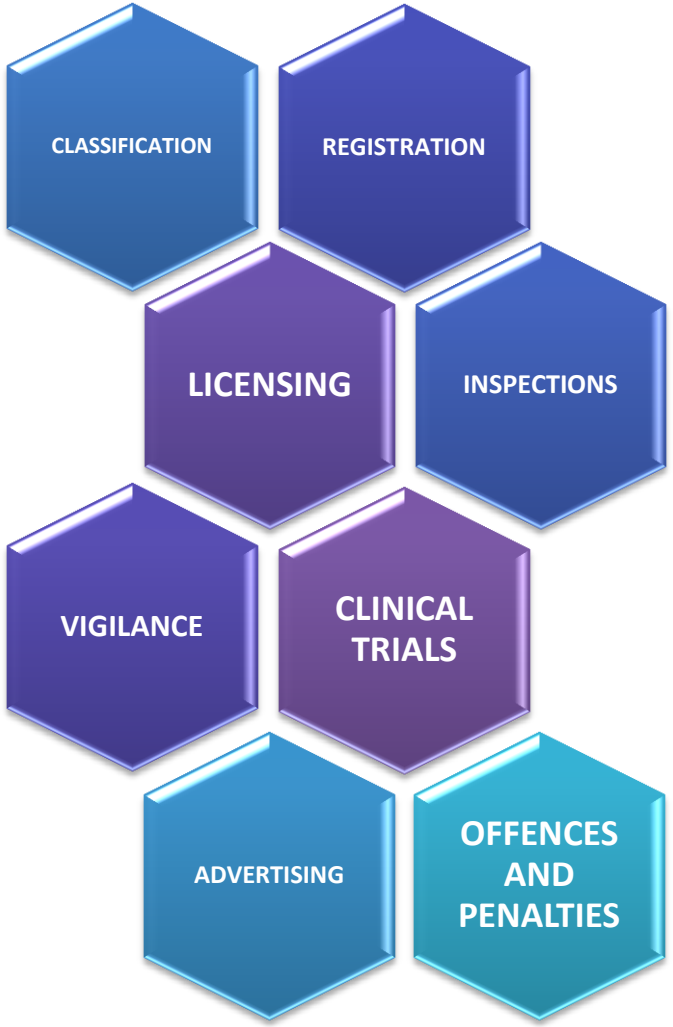
INVESTIGATIONS, OFFENCES AND PENALTIES

23. Investigations
24. Method of taking samples during investigation, certificate to be issued and reporting of analysis results
25. Compliance with requirements
26. **Offences and penalties**

TRANSITIONAL ARRANGEMENTS

27. Transitional arrangements - unregistered medical devices

South African Regulatory Road Map - Phased Implementation



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SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

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- **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

Submitting the Application

- Cover Letter on company letterhead
- Hard copy (printed copy) of the application
- Initialled by the Authorised Representative on each page
- Electronic version (in MS Word format)
- Requirements for CD
- Proof of payment x 2
  - (Change in Account Holder Name)
- CV of Authorised Representative
- Quality Manual /Site Master File

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- **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

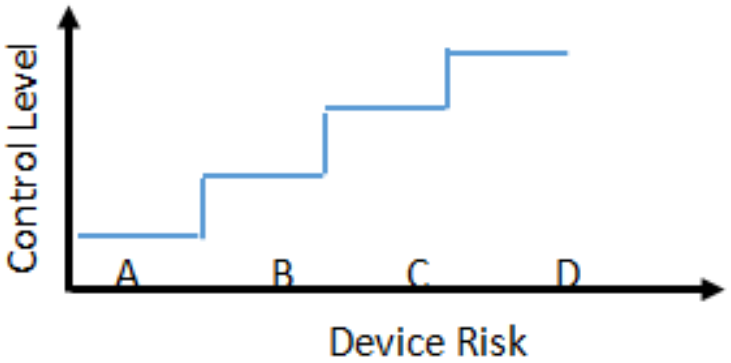
Authorised Representative

"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 11: Classification of Medical Devices

- Class A – Low Risk
- **Class B – Low-moderate Risk**
- **Class C – Moderate-high Risk**
- **Class D – High Risk**



- Classification is based on design and intended use
- Manufacturer/Distributor is responsible for indicating the classification of each medical device, listed on licence application form
- Where the classification of a medical device or IVD places it in more than one class it will be placed in the higher class
- Classification of medical devices will be confirmed by SAHPRA at the time of registration

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REGISTRATION

Call-up Plan (To be published: Communication to Industry)

Fees (To be published for comment)

Essential Principles Checklist (To be published for comment)

Application forms for registration

ZACH1.04: Administrative Information Application Form

MDTD01: Application & Check List For Registration of an *In Vitro* Diagnostic Medical Device (IVD)

MDTD02: Application & Check List For Registration of a Medical Device (Non-IVD)

To be published for implementation

Guidelines

8.08 Medical_Device_IVD_Technical_Dossier

8.09 Medical_Device_non-IVD_Technical_Dossier

To be published for implementation

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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

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Request For Designation

Include:

- Cover letter
- Table of Contents
- Supporting Motivation
- Attachments in correct sequence

Binding:

- Use of lever-arch files and ring binders is not accepted
- Use of metal fasteners should be avoided
- May not exceed 30 A4 pages

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Request For Designation

- The identity of the owner and Authorised Representative or Responsible Pharmacist, including company name and physical address, establishment licence number (Act 101), company contact person, designation of the contact person, email address and telephone number;
- A description of the borderline product, including:
  - Common, generic, or usual name of the borderline product and all component products or ingredients;
  - Classification or schedule of the borderline product and all component products or ingredients, if applicable;
  - Proprietary name of the borderline product;

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Request For Designation

- A description of the borderline product, including (continued):
  - Identification of any component or ingredient of the borderline product that already has received premarket approval or is registered with any Regulatory Authority, is marketed as not being subject to premarket approval, or has received any type of exemption.
  - The chemical, physical, or biological composition;
  - Status and brief reports of the results of developmental work, including animal/ other testing;
  - Description of the manufacturing processes, including the sources of all components or ingredients;

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Request For Designation

- A description of the borderline product, including (continued):
  - Proposed intended use or indications;
  - Description of all known modes of action, the owner's(s) and Authorised Representative's or Responsible Pharmacist's identification of the single mode of action that provides the most important therapeutic action of the product (i.e. the primary mode of action), and the basis for that determination;
  - Schedule of the active ingredient(s) and concentration per standard dose / application / use (where applicable) and duration of use;
  - Dose and route of administration of a medicine or biologic;

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Request For Designation

- A description of the borderline product, including (continued):
  - Instructions For Use for a medical device;
  - Risk assessment and risk management plan for the borderline product (refer ISO14971);
  - Description of related products, including the regulatory status of those related products;
  - Proposed claim(s);
  - Any other relevant information and
  - Summary checklist for Designation.

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- **EXEMPTIONS**
  - **SECTIONS**
    - **18A**
    - **18B**
    - **22G**
  - **December 2018**

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Thank You