UPDATE: Regulatory Framework for Medical Devices in South Africa

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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 on the regulatory oversight of Medical Devices
- Provides for the licensing of Scheduled substance Manufacturers and Wholesalers
- Status of the amendment: President signed the amendment - not yet promulgated
- Promulgation: June 2017

- Regulations for Medical Devices & IVDs:
  - Publication 9 December 2016, Government Gazette No 40480, No 1515
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

- Clinical Trials
- Licensing
- Vigilance
- Registration
- Inspections
- Classification
- Advertising
- Offences and Penalties

SAHPRA
South African Health Products Regulatory Authority
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
South African Regulatory Road Map - Phased Implementation

• REGISTRATION
  – Call-up Plan (to be published in June 2018)
  – Fees (to be published in July 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 for registration
  – To be published for implementation in June 2018
  – ZACH1.04 / MDTD01 / MDTD02
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 (Grace period)
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
- CV of Authorised Representative
- Quality Manual /Site Master File
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
South African Regulatory Road Map - Phased Implementation

• 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 July 2018
South African Regulatory Road Map - Phased Implementation

• 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
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.
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.
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Thank You