An Elsevier Indexed Journal ISSN-2230-7346

Journal of Global Trends in Pharmaceutical Sciences

MEDICAL DEVICE AND IVD'S: REGULATIONS IN SOUTH AFRICA

Kaushik Devaraju*, Balamuralidhara V., T. M. Pramod Kumar, Shashank N

Department of Pharmaceutical Regulatory Affairs, JSS College of Pharmacy, Mysuru,JSS Academy of Higher Education and Research, India

***Corresponding Author E-mail:kaushik.devaraju@gmail.com**

ARTICLE INFO

Medical Device and IVD's South Africa

ABSTRACT

The Medicines and Related Substances Act, 1965(ACT 101 of 1965), has brought tremendous changes in the field of medical device regulations in South Africa. As South Africa is considered emerging countries in Pharmaceutical Regulatory field the new regulation has brought more edges towards that. Around 90 percent of the total South African market is mainly contributed by multinational healthcare company. Some of the key points of new regulations are risk based classifications and registration, License to manufacture, Import, Export or act as distributor or wholesaler of Medical Device and IVD's, Adverse event reporting and vigilance, Advertising and custom made medical devices are few. The main impact can happen only on enforcement of regulations. This article has brought the recent regulations and updates regarding the medical device regulations of South Africa.

INTRODUCTION

The MCC is a constitutional body which is allotted by the ministry of health. The foremost of Mcc id to guard the community by make sure of all products Medical devices, IVDs, sold and used in SA for safe and effective to meet up adequate standards of quality. Medicines and related substances act 1965 take care of registration of products(MDs,IVDs). Review of all product claims and its assessment done by Council expert committee.

Medical Device Market: Medical device market in SA continues to be lead by US in all categories and projected to develop at a CAGR of 8.97% for the duration of 2018-2024.

Changes in the regulation of medical devices: The transformation in the regulations of MDs is of series from the maker to importer, exporter, of high-low risk products. And the changes include:

- Introduction of new licensing needs
- Sketch out application process
- Develops procedures for registration of products.
- Changes in labelling and advertising

Medical device an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease or for detecting, measuring, restoring, correcting or modifying the structure or function of body for some health purpose.

***In vitro* diagnostic**: is a device which is used for the in vitro examination of specimens derived from human body to provide info for diagnostic, monitoring or compatibility purposes.

Classification of medical devices and IVDs

Device has to categorize according to classification rules as per guidelines by maker based on

- Anticipated use
- Height of risk
- Extent of spreadness
- Period of use

KEY ELEMENTS FORTHE REGULATORY CONTROL OF MEDICAL DEVICES AND IVDs[6]

- The key elements of the regulatory control of medical device and IVDs include:
- License to manufacture, import, and export
- Quality safety and performance of device must meet up with standards before placing in market.
- Device categorization upon extent of hazards
- Alternative ways to exhibit conformity.
- choice of familiar principles
- Live examine of existing products accessible in market place.
- Manage developing progression of MDs and IVDs.
- Products to be registered as innermost tip of control for lawful deliver of devices
- Fine for violation of rules
- Remedial measures to be adopted in case of crisis in products.

"Custom made medical device" means a medical device: These are the devices that are being similar to products which exist in market but with customs particularly developed for specific conditions based on the prescriber needs by a health care professional.

Details to be visible in register of MDs or IVDs[2]

- Forename of the device
- Class and model of device
- Manufacturer details
- Registration no allocated
- Anticipated use of device
- Date of registration
- Provisions of listing of device.
- Nomenclature system code

Who wants Authorization?

- Maker.
- Trader
- Dealer
- Merchant

Importation of medical devices and IVDs into the Republic:

- Imports of products can be done via one of the port :
- Cape Town International Airport or harbor.
- Port Elizabeth Airport or harbor.
- King Shake International Airport or Durban harbor. or
- OR Tambo International Airport.
- Devices can be imported for maintenance, repair, refurbishing, and service.

Requirements:

- Registered license.
- Name of manufacturer, device, and address.
- Valid manufacturing license

License to manufacture, Import, export or act as a distributor or wholesaler of medical devices or IVDs: A maker, dealer, trader, or merchant have to apply license application to council to market device.

- The administrator must have separate register for each type of licenses.
- Details of name, address, license number to enter.

- Yearly once the license have to be renewed
- The changes have to inform to administrator in writing by listing the changes that have been made.

Name of the licensee to removed in the following cases:

- If the authorization holder doesn't obey the provision of license.
- Agent fails to manage manufacturing or distribution..
- Fails to fulfill the said statements by the authorization holder.

Period of validity of license and renewal of license: Applicable for 5 years from the date of registration.

- Renewal application has to be submitted before 90 days.

INVESTIGATION: The Council may conduct an investigation with regard to a medical device or IVD, its

Manufacturer, distributor or-wholesaler if-

- The medical device or IVD is recalled in South Africa or any other country;
- A medical device or IVD adverse event is reported in South Africa or any other
  Country;
- The medical device or IVD is suspected or found not to comply with the requirements
  Of the act;
- There is an international alert with regard to the medical device, IVD or the
  Manufacturer of the medical device or IVD; or
- For any other reason, the Council considers it necessary to conduct an investigation on the medical device or IVD.

Conduct of clinical trial and clinical Investigation

A. A person desiring to initiate or conduct-

- A clinical trial or clinical investigation in respect of an unregistered medical device;
- A clinical performance assessment for an IVD; or
- A new Intended purpose of a registered medical device or IVD.

Must apply to the Council on a form, determined by the Council, for authorization to conduct

The clinical trial, clinical investigation or clinical performance assessment

B. The application referred to in sub-regulation (1) must be accompanied by the prescribed fee and must contain at least the following information:

- A clinical investigation plan or clinical trial or clinical performance assessment for an
- IVD protocol;
- An investigator 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;
- The Curriculum Vitae of the investigator;

C. The clinical investigation plan, clinical trial or clinical performance assessment for an IVD protocol referred to in sub-regulation (2)(a) must co~taln at least the following information:

i. The. number of human or animal subjects, as applicable, to ba involved in the Clinical investigation, clinical trial or clinical performance assessment far an IVD

- the name of the investigator who must be-
- An appropriately qualified and competent person approved by the Council
- Resident in !he Republic; and
- In charge of the sites where. clinical trials or clinical performance assessment

- For an IVD are conducted;

D. The person conducting the clinical investigation, clinical trial or clinical performance

Assessment for an IVD must submit to the Council-

- Progress reports after every six months from the date when the· clinical investigation,
  Clinical trial or clinical performance assessment for an IVD was started, and 30 days
  After the completion or termination of the clinical investigation, clinical trial or clinical performance assessment for an IVD; and
- Adverse event reports immediately or as soon as practically possible.

Labelling of medical device or IVD

- The label of each medical device or IVD must contain the following particulars:
  - The name or trade name of the medical device or IVD;
  - Product description and intended use;
  - A product catalogue code, where applicable;
  - The name and business address of the manufacturer;
  - The name and business address of the holder of the certificate of registration;
  - Where appropriate, an indication that the medical device contains or incorporates a scheduled or biological substance;
  - The lot number, where applicable;
  - The serial number, where applicable;
  - For accessories, the serial number may be substituted with- a control number and for software it may be substituted with a version number;
  - The expiry date, where applicable;
  - Where there is no indication of the expiry date, the manufacturing date;
  - An indication of the special storage or handling conditions applicable;
  - If the medical device Is supplied sterile, an indication of its sterile state and, where appropriate, the sterilization method;
  - Where relevant, 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;
  - Warnings or precautions, where applicable;

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

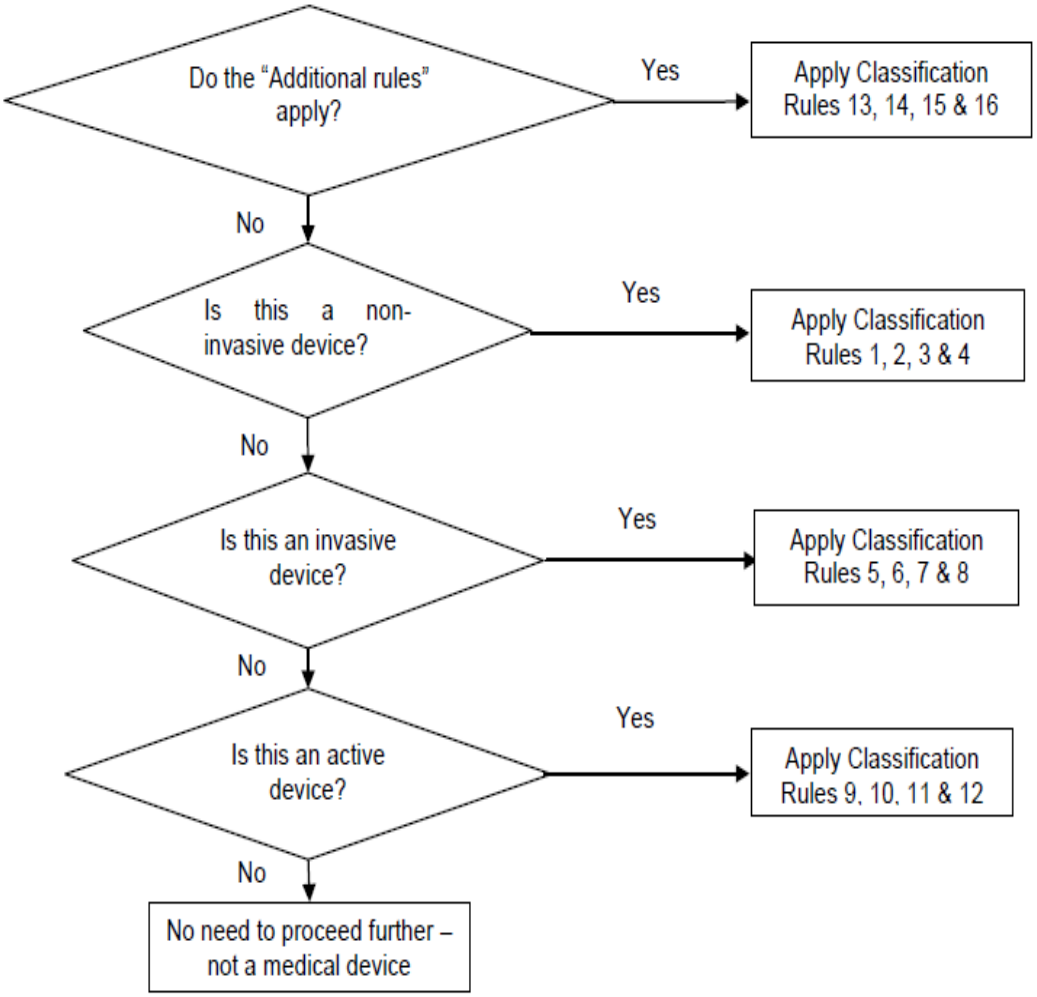
  - On the medical device or IVD itself or
  - On the packaging of each unit; and
  - On the packaging of multiple medical devices or IVDs.

- 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..

Custom made medical device: A custom made medical device must be manufactured and sold in compliance with theguidelines applicable to medical devices.

Compliance with requirements: A medical device or IVD must conform to the standards and specifications which were furnished to the Council on the form

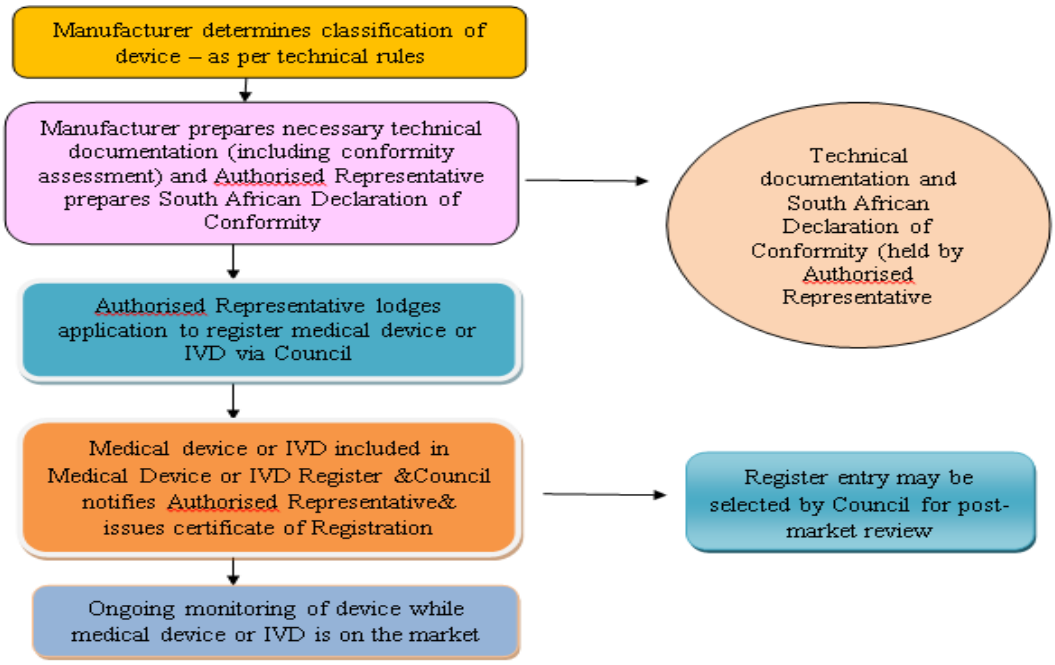
referred to in regulation 8 and which .form has been accepted by Council in respect of the medical device or IVD.



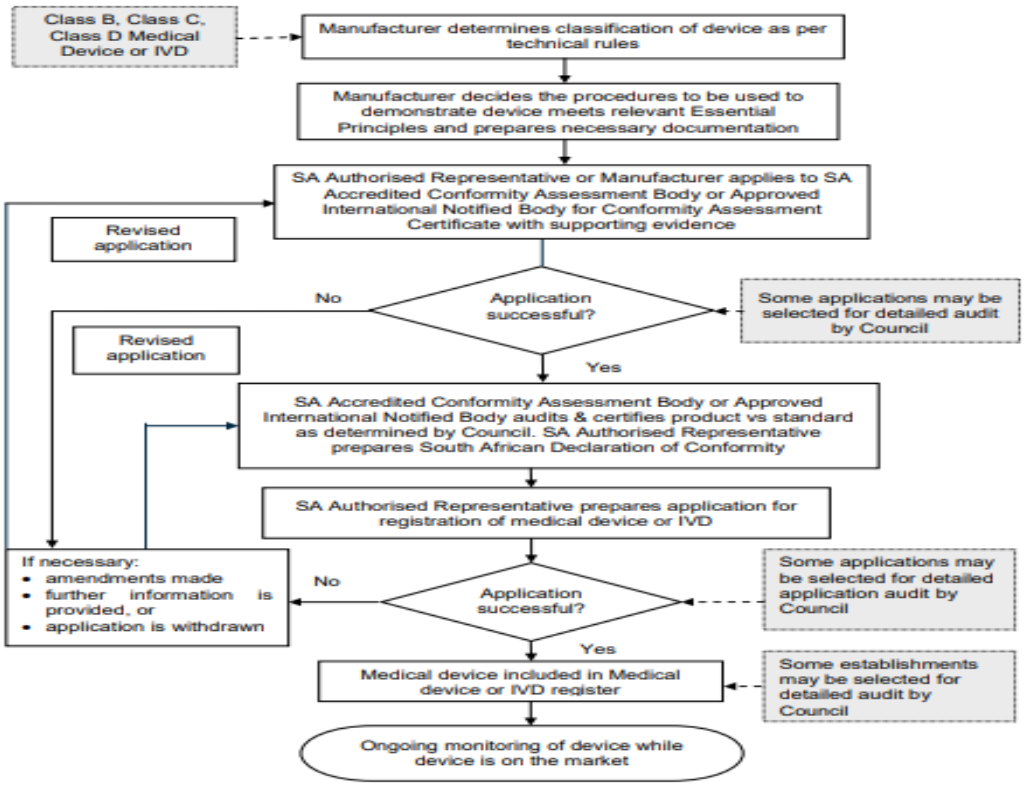
Classification of medical devices and IVD

Classification rules[2]

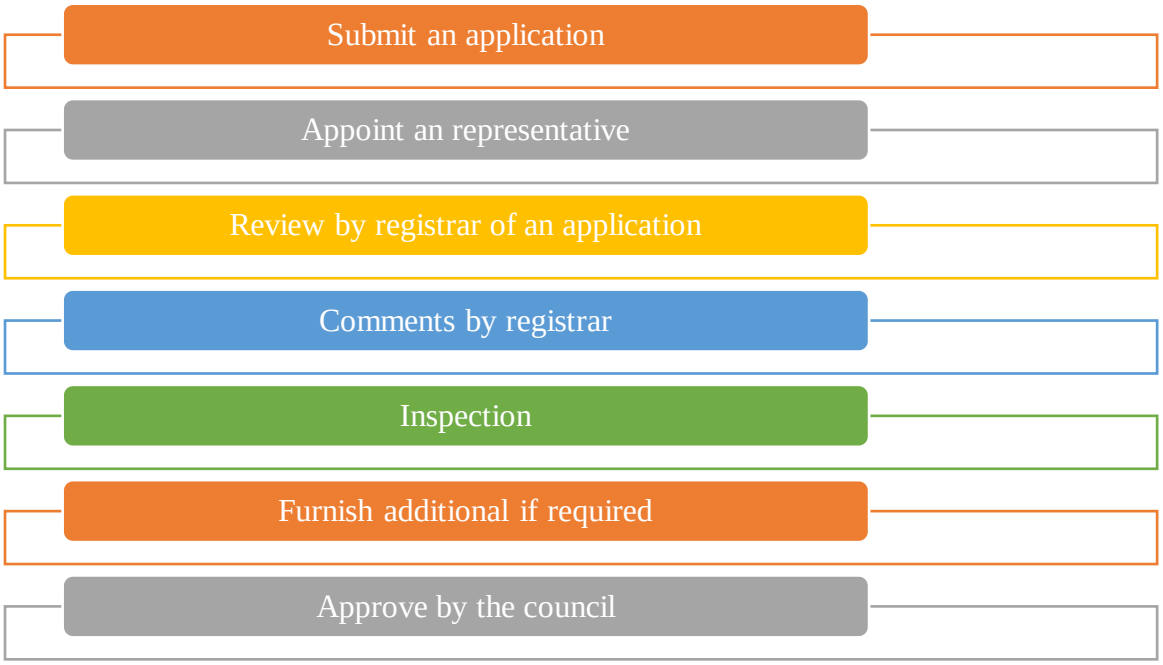
Classification	Level of risk
Class A	Low risk
Class B	Low-moderate risk
Class C	Moderate to high risk
Class D	High risk(where risk relates to the patients, user to public health)



I Process to supply a Low risk Class A medical device or IVD in South Africa



Process to supply a Class B, Class C, and Class D medical device or IVD in South Africa.



Advertising of medical devices or IVDs: The following requirements apply to an advertisement of a medical device or IVD:

- Only Class A and Class B medical devices and IVDs may be advertised to the public or a lay person.
- A written advertisement for a medical device or IVD must contain:
- The name of the medical device or IVD
- In the case of a registered medical device or IVD, the registration number allocated to the medical device or IVD
- When a Class C or Class D medical device or IVD is advertised for th8 first time to prospective user, written information, which must include at least the information referred to in regulation 23 or regulation 24 as the-case may be, must simultaneously be given to the person whom the oral, electronic or printed advertisement is directed.

Offences and penalties: A person who fails to comply with, contravenes the provisions of, or willfully furnishes incorrect information in respect of-

- ✓ Regulations 3 or 4 with regard to the importation or transmission of medical device or IVDs;
- ✓ Regulation with regard to the license to manufacture, act as a distributor or act as a wholesaler of medical devices or IVDs;
- ✓ Regulation 14 with regard to the destruction of medical devices or IVDs;
- ✓ Regulation 16 with regard to the conduct of clinical trials
- ✓ Regulation 21 with regard to the advertising of medical devices or IVDs;
- ✓ Regulation 22 With regard to the labeling of medical devices or IVD
- ✓ 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;
- ✓ A person who sells a medical device or IVD that has expired is guilty of an offence and upon conviction is liable to a fine, or to imprisonment for period not exceeding 10 years.

CONCLUSION:

The Medicines and Related Substances Act, 1965(ACT 101 of 1965) is an overwhelming signs for the South Africa regulatory authority. As South Africa is emerging market, the success rate of regulations depends only on the enforcement of the act; there is need for the enforcement. South Africa can look for other countries wherein already medical device regulations are incorporated for better regulatory delivery.

REFERENCES:

1. Vaughn Harrison and Mandi Krebs et al Medical devices – South Africa's changing landscape Available athttps://www.hlregulation.com/2017/06/05/medical-devices-south-africas-changing-landscape/
2. https://www.sahpra.org.za/documents/838804628.01_General_Guideline_Medical_Device_IVD_Aug15_v2_for_comment.pdf
3. https://www.prnewswire.com/news-releases/south-africa-medical-device-market-is-expected-to-grow-at-a-cagr-of-897-percent-during-the-forecasting-period-2018-2024-300584763.html
4. T Saidiand T S Douglas et al Medical device regulation in South Africa: The Medicines and Related Substances Amendment Act 14 of 2015 Available at

http://www.samj.org.za/index.php/samj/article/view/12221

5. Kirby N. et al A new regulatory regime for medicines comes into force in SA. 2017. Available at: https://www.timeslive.co.za/news/2017-06-15-a-new-regulatory-br-regime-for-medicines-br-comes-into-force-in-sa/
6. Brian Goemanset al New South African Medical Device Authority EstablishedAvailable at :https://www.emergobyul.com/blog/2017/06/new-south-african-medical-device-authority-established