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Regulatory Requirements For Medical Devices In India As Per CDSCO Comparison with South Africa

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ABSTRACT

The medical device market in India is a sunrise sector in the pharmaceutical industry and has achieved a milestone in the last few years securing 4th position in the medical device market in Asia with increasing foreign direct investments through governments. Make in India Campaign 2017 and PLI (Product linked incentive) schemes. To enter the medical device market in any country, one has to go through different procedures and regulatory requirements of that country. Medical devices are regulated in India by the DCGI (Drug Controller General of India) under the CDSCO (Central Drug Standard Control Organization). These rules and regulations covers various aspects of device related regulations, including classification, registration, manufacturing and import, labeling, sales, and post marketing requirements, etc. This study is aimed to review and compare the regulatory requirements of South African country with India. Harmonization of medical devices registration across the markets of these two country is essential to overlay way for their easy approval and also in dealing with the withdrawn issues related to quality, safety, and performance.

Keywords: CDSCO, SAPHRA, Notified devices, Medical device rules 2017, International regulations, Drug and Cosmetic act 1940 and rules 1945, Medical device

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INTRODUCTION

A medical device (MD) is an instrument, apparatus, implant, in-vitro, reagent or similar or related article that is used to diagnose, prevent, or treat disease or other conditions. Medical devices have been used to treat and diagnose disease since antiquity.

There is evidence of trephination having been performed in Neolithic times and instruments have been excavated in Jericho from 2000BC.

- It does not have its purposes through chemical action within or on the body.
- Medical devices vary greatly in complexity and application and its design constitutes a major segment of the field of biomedical engineering.
- Today devices are widely used in all branches of medicine, surgery and community care.
- Global medical devices market size was valued at USD 62.6 billion in 2021 and is poised to grow from USD 63.4 billion in 2022 to USD 134.56 billion by 2030, growing at a CAGR of 11.35% in the forecast period (2023-2030).

A medical device is defined according to schedule M-III creates a specific definition of medical devices as separate from drugs, unlike a drug, a medical device is defined as a medical tool "which does not have achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means".

Aims and objectives:

The aim of work is to study about recent advancement in Indian medical rules and regulation concerning or related to medical devices including:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function.
- To evaluate the rules and regulation/regulation requirements required for medical devices and Drugs and cosmetic act 1940 and rules 1945, devices rules 2017.
- To list out major changes in the regulation of medical devices with implementation of medical devices rules 2017.
- To study regulation to provide quality in medical devices, DMF requirements for MD.

DISCUSSION:

Medical Devices are considered a fundamental component of Health Systems; the benefits they

can provide continue to increase as they're essential to prevent, diagnose, treat and rehabilitate illnesses and diseases in a safe and effective way.

CLASSIFICATION:

Classification of MD as per Indian CDSCO regulations-

The Central Drug Standard Control Organization (CDSCO) in India classifies medical devices into four categories based on level of risk they pose to patients and users.

- Class A -Devices involving low risks levels, It includes Stethoscopes, bandages, and other medical devices which cause no harm to the users.
- Class B -Devices involving low to medium risk, It includes Blood pressure monitors, Syringes and needles that may cause harm to the patients but not life threatening.
- Class C -Devices involving moderate to high risk, It includes artificial heart valves, orthopedic implants, catheters that have potential to harm a patient if it is malfunctioned.
- Class D -devices involving high risk, It includes pacemakers, heart-lung machines, and ventilators which are very critical to the health and survival of patients and can cause harm or death if they malfunction.

Classification of MD as per South African regulations-

- Class A Low risk, Bandages and basic wound dressings.
- Class B Low–moderate risk, Powered wheelchairs and electrotherapy devices.
- Class C Moderate high risk, Diagnostic X-ray equipment & implantable hearing aids.
- Class D High risk, Implantable heart pacemakers and insulin pumps.

REGULATIONS OF MEDICAL DEVCES IN INDIA:

In India medical devices are governed by CDSCO (Central Drugs Standard Control Organization) which is regulated by Directorate general of health services, Ministry of health and Family Welfare, Government of India.

In India medical device rules are regulated by:

1. Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945
2. Medical Devices Rules, 2017
3. Medical Devices (Amendment) Rules, 2020

India's medical device regulation structure

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Ministry of health and welfare

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Drug controller general of India

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Central drugs standard control organization (CDSCO) –medical devices division

The Central and State Licensing Authority with the prior approval of the Central and State Government, by an order in writing, delegate all or any of its powers to any officer under its control.

The controlling officer, DCGI (Drug Controller General of India) supervise and give instructions to any officer subordinates.

REGULATIONS OF MEDICAL DEVICES IN SOUTH AFRICA:

In South Africa the MCC(Medicine Control Council) has been replaced as authority by SAPHRA(South African Health Products Regulatory Authority),which is an organ of state outside of the public service, subject to the provisions of the Public Finance Management Act 1 of 1999.

SAPHRA is an entity of the National Department Of Health, whose function is to ensure the periodic re-evaluation and monitoring of medical devices and IVD devices.

Minister of health

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SAPHRA board

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Chief executive officer

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Technical functions and operational support.	Strategic planning and quality management.

Manufacture, import and licensing of medical device for sale or for distribution in India:

The application for the manufacture of medical devices should be submitted through online portal of the ministry of health and family welfare. The central licensing authority (CLA) may conduct an inspection of a manufacturing location.

1. Application for the grant of license for manufacture of the notified medical Devices in the country shall be made in Form 27 to the State Licensing Authority, accompanied by the requisite fee in the form and manner as prescribed in the said Rules along with a copy to the office of DCG (I)
2. A time period of 60 days would be provided for making the application for manufacture from the date of publication of these guidelines.
3. The most common standards for the medical devices manufacturing include: ISO 9001, which is the general standard for quality management.

Importers, stockiest, and retail sellers of Medical Devices shall obtain appropriate sale licenses from the State Licensing Authorities for these medical devices within a period of 3 months form the issue of these guidelines. In India, for the import and registration of medical devices, import permits are essential. Therefore, an individual who is likely to Import any medical devices to India should obtain a registration certificate and import permit. Both production and import license applications are dealing with an online portal, SUGAM an online licensing program is part of the MoHFW. SLA shall control the manufacturing authorization for products of Class A and B medical device, and perquisite for the Class C and D licenses will be referred to the CLA. A Quality Assurance Report (QAR) of Class B, C and D goods must be published in accordance with manufacturing license; By comparison, a QAR for medical devices under Class A has to be issued within 4 months from the authorization date of the license for manufacture. In the event that products were not shipped into the nation before the date of the notification, the import is not authorized. The permission of the competent authority is needed for the importation of medical devices into India. Certain products that are already in use are placed introduced in the market for a certain period of time until the request made is denied or accept.

MANUFACTURE, IMPORT AND LICENSING OF MEDICAL DEVICE FOR SALE OR FOR DISTRIBUTION IN SOUTH AFRICA:

The new regulations of South Africa includes a four tier, risk based classification system for obtaining device licences for manufacturers, importers and distributors. The manufacture, importation, exportation and distribution, And also the wholesaling of medical and IVD devices, are subject to regulations, based on the level of risk and the intended use. All classes of medical devices are regulated based on the requirement for a medical device establishment license, which permits a company to manufacture, distribute or wholesale medical devices. The establishment license leads the registration of medical devices. Domestic manufacturers, distributors and wholesalers are required to apply for licences; foreign-based manufacturers are not. It is

compulsory for foreign manufacturers to provide their importers and domestic distributors with elementary device information, including Global Medical Device Nomenclature codes, Certificates of Free Sale from reference countries for Class C and Class D devices. Certificates of Free Sale or Certificates to Foreign Countries for Class B and Class D devices are needed.

The 2015 Act forbids the importation of Class B, Class C or Class D medical or IVD devices which are not registered in SA for personal use, unless authorization is approved by SAHPRA, stating the specified period and quantity. Manufacturers and distributors of moderate- to high-risk Class C and Class D devices and IVD devices are required to show proof of pre-market approval or registration for a medical or IVD device from at least one of the following regulatory authorities as part of their South African registration: the Australian Therapeutic Goods Administration (TGA), Brazil's National Health Surveillance Agency (ANVISA), Health Canada, the European Competent Authority, the Japanese Pharmaceuticals and Medical Devices Agency and the US Food and Drug Administration. The new regulations also have provisions for advanced registration, when the medical or IVD devices in question are in little supply, unavailable, or of national interest, or when the government invites an international tender and such medical or IVD devices are not already registered in SA.

Sale and distribution of medical devices, under the new Act, only registered products may be sold in SA. The new regulation is unambiguous in that a manufacturer, wholesaler or distributer of medical or IVD devices are not allowed to manufacture, act as a wholesaler of, or distribute any medical or IVD device, unless it is a holder of a valid license. The definition of 'sell' has been broadened to include advertising, thereby making it all-inclusive. The regulations forbid advertisement of any medical or IVD device, unless it complies with the prescribed requirements. The preceding regulation, the Medicines and Related Substances Control Act 101 of 1965, restricted profiting and sampling of medicines only, but the new regulations include medical and IVD devices, which means that such devices cannot be supplied and sold in terms of a bonus, rebate or any other incentive scheme.

Figure 1: In vitro diagnostic medical devices

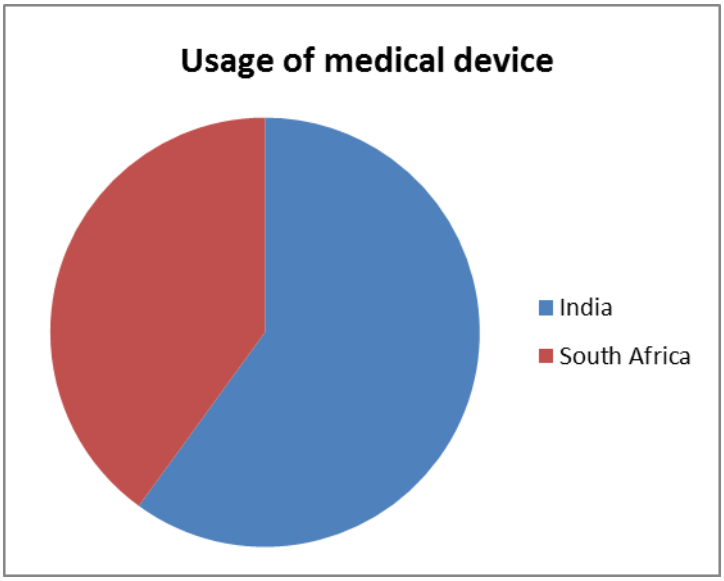

Figure: Usage of medical device

Class of medical device	Licensing Authority	Stipulated timeline for processing application	Deadline for obtaining license
Class A and B (import)	DCGI	Up to 9 months from the date of application	September 30, 2022
Class C and D (import)	DCGI	Up to 9 months from the date of application	September 30, 2023
Class A (manufacture)	State-level Licensing Authority	Up to 45 days from the date of application	September 30, 2022
Class B (manufacture)	State-level Licensing Authority	Up to 140 days from the date of application	September 30, 2022
Class C and D (manufacture)	DCGI	120 – 180 days (estimated)	September 30, 2023

COMPARISON OF REGULATORY REQUIREMENTS OF MEDICAL DEVICES IN INDIA WITH SOUTH AFRICA:

Sl.no	Requirements	India	South Africa
01	Regulatory bodies	CDSCO	SAHPRA(South Africa Health Products Regulatory Authorities)
02	Classification categories	Class A – Low risk level accreditation. It is a sole liability of producer. Class B- Low moderate l level devices. Class C- Moderate high certificate for plan and production of clinical gadgets. Class D- High risk level medical devices.	Class A – No public health risk or low personal risk. Class B – Low public health risk or moderate personnel risk. Class C- Moderate public health risk or high personnel risk. Class D – High public health risk.
03	Application submission format	Forms 44 have to be submitted according to national format.	e CTD submission
04	Approval timeline	16 to 18 weeks	6 to 8 weeks
05	Application fees	Fees is required in phase I, II, III, i.e. 50000, 25000, 25000 respectively.	Initial fee $ 1010 Annual fee of $ 282 is charged for renewal.
06	Institutional Review Board	DCGI and Ethics Committee approval required.	Drugs and Cosmetics act approval is required.
07	Regulatory Pathway	Medical devices are regulated in India by ministry of health and family welfare's CDSCO.	It is achieved by SAPHRA to the timelines historically achieved by medicines control council.
08	Performance Evaluation	Design and development validation performed for the IVDMD. A requirement for import and / manufacture of the IVDMD.	Data identifying the milestones and overall approval times for NASs registered by the South African agency during 2015 – 2018 were collected and analyzed.
09	Stability conditions	30° C / 70 % RH	25° C / 60% RH
10	Device registration process	Online registration with CLA voluntary till Oct 2021. Upload details of the devices, ISO 13485 compliance certificate and undertaking registration No. Generated.	SAHPRA will implement reliance pathways in the registration of medical devices based on the verification of registration of medical devices in other recognized jurisdictions and or pre-qualification of IVDs by the WHO.
11	Licensing	Valid CDSCO Wholesale license is required in the form of 20B and 21B. Import license is required in the form of 8 &9 to market medical devices in India.	In terms of section 22C(1)(B) of the act, the authority may, on application in the prescribed manner and on payment of the prescribed fee, issued to manufacturer, wholesale or the distributor of a medicine or medical device license to * Manufacture, import, or export; or

			* Import , distribute or export; or * Act as a wholesaler
12	Risk minimization measures	Anticipating and assessing risks, monitoring them.	»Avoidance » Retention » Spreading » Loss of prevention and reduction » Transfer(through insurance and contracts)
13	Validity of License	Valid permanently, subject to timely completion of payment before 5 yrs from the date of its issue by the SLA (State licensing authority)	Valid for 5 years

CONCLUSION

Medical device industry of India is projecting towards an edge of growth. The growth of pharmaceutical, medical tourism and the medical device sector are somewhat correlated. Though, the share of this sector is just 15% in the overall industry but that small contribution is valuable for the growth of whole industry. Understanding the regulatory reforms is imminent in India will be crucial for foreign companies looking to enter or expand the business in India's medical markets. It is hoped that the guidelines are implemented and regulated properly with effective outcome. This article highlights current regulations pertaining to applications for medical device registration certificates, medical device clinical trials, and medical device manufacturing /importation licenses

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REFERENCES

No.G.S.R. 78(E), dated 31st January, 2017, last updated 17th October, 2022. http://www.bareactslive.com/ACA

1. The Medical Devices Rules 2017, published vide Notification /act2713.htm
2. Medical devices and diagnostic CDSCO https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/
3. Indian approval process for medical devices and IVD's https://www.emergobyul.com/resources/india-approval-process-medical-devices- ivds
4. India medical device registration and approval process- CDSCO https://asiaactual.com/india/medical-device-registration/#:~:text=Medical%20device%20registration%20in%20India%20is%20overseen%20by%20the%20Central,Authority%20(NRA)%20of%20India.
5. List of notified bodies registered with CDSCO under MDR, 2017 https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_Not ices Files/ListofNotifiedmd.pdf
6. Regulation of medical devices in India
7. https://www.tuvsud.com/en-in/industries/healthcare-and-medical-devices/medical-devices- and-ivd/medical-device-market-approval-and-certification/regulation-of-medical-devices- in India.