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A New Medical Device Regulations in India –Challenges Andaway-Forward

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ABSTRACT: The Indian healthcare sector, growing at a fast pace, is expected to reach $280 billion by 2025. Medical devices, a key aspect of this sector, were previously regulated under the Drugs and Cosmetics Act, 1940. To address the regulatory gap, the Central Drug Standard Control Organization introduced the Indian Medical Device Rules, 2017, which were later amended as Medical Devices (Amendment) Rules, 2020. These rules cover various aspects of device-related regulations, including classification, registration, manufacturing, import, labelling, sales, and post-market requirements. Despite these advancements, the article suggests that on few challenges and implementation bottlenecks for the success of the legislation and further clarity and revamping of the current regulatory system are needed to harmonize standards with advanced regulation.

KEYWORDS: Indian healthcare sector, Medical devices, Drugs and Cosmetics Act, 1940 , Central Drug Standard Control Organization, Indian Medical Device Rules, 2017

I. INTRODUCTION

The Indian healthcare industry has seen significant growth and evolution over the past decade, with the medical devices sector playing a crucial role at every stage of the healthcare continuum. The current dynamics of demand and supply present a compelling case for the manufacture of medical devices in India. The 'Make in India' initiative by the Government of India provides an opportunity for the sector to reassess its operating model, identify key growth drivers, and explore potential avenues for transformative growth in the medical devices sector. (1)

Medical devices represent a multi-billion-dollar global industry with ongoing growth opportunities driven by technological advancements and innovations. However, these innovations and advancements do not always reach patients due to ambiguities in the approval process and stringent regulations imposed by health authorities. (2) One of the major challenges for companies involved in the development and production of medical devices is staying updated with regulatory requirements and incorporating them into their processes. (3)

These regulations can create hurdles for innovators, manufacturers, and exporters seeking approval for market distribution in India. (4) Medical devices are becoming increasingly important in the healthcare sector.

The Indian device market ranks among the top 20 globally and is the fourth-largest market in Asia. It is valued at approximately USD $5.5 billion and is expected to grow at a CAGR of 15 percent. (5)

The new rules are comprehensive and aim to enhance manufacturing capabilities, reduce dependence on imported products, and expand the market size. (6)

Business growth is a top priority for the Indian government. As part of the 'Make in India' campaign, the implementation of medical device regulations was a strategic move to improve the business environment and promote domestic development and manufacturing of medical devices.

The Central and State Government bodies will be responsible for implementing and enforcing the Medical Device Rules (MDR) 2017. The Drugs Controller General of India (DCGI) will oversee medical device approvals, clinical trials, import licenses, and device classifications. (8)

The changes brought about by the Medical Devices Rules, 2017 are expected to encourage more Multinational Companies (MNCs) to establish

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medical device manufacturing facilities in India. This, in turn, will expedite the availability of innovative products to patients in India. (7)

Significance of Medical Devices:

Medical advancements have significantly decreased rates of disease and death, with tools such as cosmetic treatments, dental equipment, and cardiology devices playing a crucial role in diagnosing and treating illnesses.

Medical devices, which include items like medical gloves, bandages, syringes, condoms, contact lenses, disinfectants, X-ray equipment, surgical lasers, pacemakers, dialysis equipment, baby incubators, and heart valves, are an integral part of contemporary healthcare. They are vital for patient care in various settings, from bedside care to rural health clinics and large, specialized hospitals.

The medical devices market is experiencing double-digit growth, with cardiac devices alone seeing a growth rate of 20%. In India, the market growth is estimated to be between 10-15%, driven by factors such as affordability, heightened healthcare awareness, improved hospital infrastructure, and evolving disease patterns. The quality of medical devices is largely governed by regulatory systems, with 85% of these devices being manufactured in the USA, Japan, and the European Union.

CurrentRegulatoryScenario:

A unique aspect of classifying medical devices as drugs is that it enables the National Pharmaceutical Pricing Authority to set a maximum price for the medical devices it considers necessary to price cap, in line with the Drug Price Control Orders. In February 2017, the price of coronary stents in India was reduced by 74% for bare metal stents and by 85% for drug-eluting stents, following reports that many hospitals had inflated the price of these stents for profit.

The government has expressed its intention to place several more medical devices under price control. The draft National Medical Devices Policy 2015 also tackles affordability issues by suggesting that medical devices be included as a separate list of commodities under the Essential Commodities Act, 1955, and by proposing the establishment of an independent National Medical Devices Authority under the supervision of the Department of Pharmaceutical.

The Drugs and Cosmetics Act, which primarily regulated notified devices, has been criticized for its limited applicability to non-notified devices, leading to the spread of substandard devices and impeding the industry's growth. Emerging technologies were not recognized as medical devices, affecting developers and manufacturers. Despite 100% FDI being permitted under the automatic route, the industry was not fully realizing its investment potential. The new medical device rules, which were implemented in January 2018, have provided the medical devices and in-vitro diagnostic devices (IVD) industry with a distinct regulatory identity. The rules separate devices from drugs, ensuring the safety, quality, and performance parameters of devices sold within the country. The new rules establish a system for appointing Notified Bodies to verify and assess the QMS of medical device manufacturers, accredited by the National Accreditation Board for Certification Bodies (NABCB). Mandatory certifications by the Bureau of Indian Standard (BIS) and International Standards Organization (ISO) will ensure quality standards are adhered to, promote domestic manufacturing, and require product testing and certifications recognized by the Indian government. The rules focus on device classification, clinical investigations, and registration and post-marketing license requirements and procedures.

Definitionofmedicaldevice:

The introduction of the Medical Devices Rules signifies a new phase for the Indian medical devices industry.

For the first time, they are being recognized as distinct from drugs. According to Rule 3(b), a medical device is defined as:

(A) Substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bags with or without anticoagulant, covered under sub-clause (i).

(B) Substances including mechanical contraceptives (condoms, intrauterine devices, and tubal rings), disinfectants, and insecticides notified in the Official Gazette under sub-clause (ii).

(C) Devices notified from time to time under sub-clause (IV) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

The Rules also categorize Active Medical Devices as medical devices that depend on energy sources other than electrical energy. Active Diagnostic Medical Devices are defined as devices

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used for detecting, diagnosing, monitoring, or treating physiological conditions.

Active Therapeutic Medical Devices are defined as devices used to support, modify, replace, or restore biological functions or structures for the treatment or alleviation of illnesses, injuries, or handicaps. These devices may be powered by electrical, biological, or gravity-generated energy.

Classification of Medical Device:

Classification is based on the risk associated and the intended use. In case of combination devices, the rules for classification of such devices are applicable for individual devices.

Medical Devicesin India are classified;

a) Based on risk associated.
b) Based on intended use.

Based on risk associated, medical devices are classified into 4 classes:

- Class A(Low Risk Devices)
- Class B(Low Moderate Risk Devices)
- Class C(Moderate High Risk Devices)
- Class D(High Risk Devices)

Based on the intended use, medical devices are further classified into four types:

- Non-invasive Devices
- Invasive Devices
- Surgical Invasive Devices
- Miscellaneous Devices

India Medical Device 2022

The medical devices industry in India is currently valued at USD 5.2 billion, contributing 4-5% to the USD 96.7 billion Indian healthcare industry. With approximately 750-800 medical device manufacturers in the country, the average investment is Rs 170-200 million, and the average turnover is Rs 450-500 million. The industry has seen steady growth, increasing from USD 2.02 billion in 2009 to USD 3.9 billion in 2015 at a CAGR of 15.8%. According to industry estimates, the Indian medical devices market is projected to grow to USD 50 billion by 2025. Presently, India ranks among the top 20 global medical devices markets and is the fourth-largest medical devices market in Asia, following Japan, China, and South Korea.

- **Market Factors**: The growth is driven by a growing and aging population, an expanding income base and associated disposable income, increased socio-economic inclusion of rural and underprivileged populations in the mainstream economy, heightened manufacturing innovation to create customized products for all income segments, changing disease prevalence patterns (e.g., early onset of diabetes and heart diseases), and growing awareness among the middle class to focus on early detection and disease prevention. (20)
- **Non-Market Factors**: These include the development of infrastructure, favorable regulations, FDI inflow, outsourcing of manufacturing and R&D activities to India, and government initiatives to improve healthcare access through insurance schemes such as RSBY (RashtriyaSwasthya Bima Yojana), Aarogyasri, etc.

Here are some key features of the New Medical Device Rules, 2017:

- The regulations apply to medical devices and in-vitro diagnostic medical devices.
- The previous list of 15 devices has been replaced by four classes that categorize all medical devices to be sold in India.
- License applications for sales and distribution can be completed online.
- Notified Bodies will audit manufacturing sites and products to ensure they meet standards.
- Foreign manufacturing sites may be inspected by India's Central Licensing Authority.
- Starting in 2020, approved medical devices must have a unique identifier.
- Medical devices new to the Indian market are subject to special regulations.
- Not all medical devices will require clinical investigation.
- Application fees have increased.
- Registration Certificates are valid for five years. (14)

This project offers an overview of the New Medical Device Rules, 2017, released by India's Ministry of Health and Family Welfare for implementation from January 1, 2018. It also provides recommendations for addressing identified gaps in the rules, highlights less obvious features of the regulation, and lists changes to the regulations.

ROLE OFMEDICAL DEVICESIN HEALTHCARE:(1)

Medical devices have expanded their role in enhancing healthcare in several ways:

- **Screening and Diagnosis**: The use of portable

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devices has increased the accuracy and complexity of screenings and diagnoses, enabling care at home and improving patient outcomes and satisfaction outside of healthcare facilities.

- **Treatment**: Advanced devices facilitate the treatment or cure of diseases, thereby reducing the duration of hospital stays.
- **Restoration**: Advanced rehabilitation devices aid in restoring patients from ill health to normal health.
- **Monitoring**: Devices that monitor health indicators regularly at home help minimize hospital visits and stays.

The figure1describes the role of medical devices in healthcare.

Figure1: Role of Medical Devices in Healthcare

MEDICALDEVICECATEGORIES/SEGMENTS:

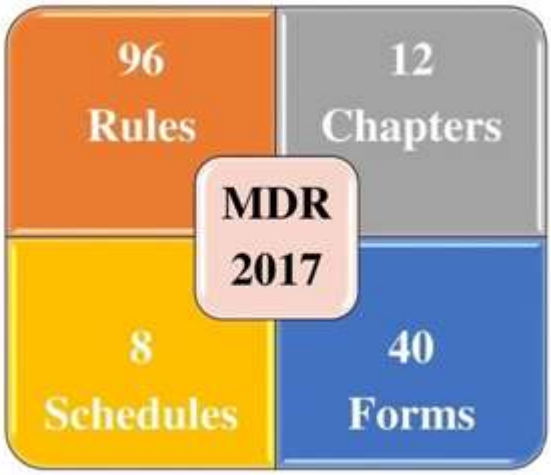
Indianmedical deviceindustryhas broadlyclassified into 4major segments ,namely

a) Instrumentsandappliances
b) Consumablesandimplants
c) Diagnosticimaging
d) Patientaidsandothers

MEDICALDEVICERULES–2017:ANEWREGULATORYFRAMEWORK (20)

The new Medical Device Rules contains, following sections as illustrated in figure 2.

Figure2: Overview of MDR



Online Portal

"CDS COMEDICAL DEVICE ON LINE PORTAL"

Thisisane-GovernancesolutionforCDSCO.Websitelink:https://cdscomdonline.gov.in

The portal is designed to enhance the implementation of MDR-2017 and regulate medical devices by offering the following features:

- Submission of online applications/forms.
- Tracking the status of submitted applications.
- Granting or rejecting permissions, approvals, or licenses.
- Submission of supplements or amendments.

LEGAL REGULATORY ADMINISTRATION:(20)

The list of authorities and their duties are described in table 10.

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Table10:Legal Regulatory Administration

AUTHORITIES	DUTIES
Central Licensing Authority	Import of all classes of medical devices. Manufacture Class C and D devices. Approval of investigational medical devices and clinical investigation.
State licensing Authority	Manufacture Class A and D devices. Sale and distribution of all classes of medical devices.
National Accreditation Body	Accredit and certify Notified Bodies by performing conformity assessment. Periodic audit of notified bodies.
Notified Body	Audit of Class A and B devices. Audit of Class C and D devise (after experience of two years)
Central Medical Device Testing Laboratories	Testing and evaluation of medical devices

IMPORTOFMEDICALDEVICES: (20)

- A licensed manufacturer must submit an application for an import license to the Central Licensing Authority (CLA) via an online portal. The application should be submitted using Form MD-14.
- **Fees**:
  - Class A: One site-$1000 and each distinct MD-$50
  - Class B: One site-$2000and each distinct MD-$1000
  - Class C or D: One site-$3000 and each distinct MD-$1500
  - Inspection of overseas manufacturing site :$6000
- The import license is issued through Form MD-15. The CLA conducts an inspection of the overseas manufacturing site, either by itself or by another notified body to whom the power has been delegated.
- In the case of a test license for the import of MD for testing, evaluation, or clinical investigation, the application is submitted to the CLA through Form MD-16.If the documents submitted are satisfactory, the CLA grants the license through Form MD-17.
- An application for the import of a small quantity of investigational MD for the treatment of patients with life-threatening diseases is made to the CLA through Form MD-18, accompanied by relevant documents and specified fees. After scrutinizing the submitted data, the CLA grants a license to import investigational MD through Form MD-19.
- Similarly, for importing MD for personal use, an application is made to the CLA through Form MD-20, accompanied by relevant documents, proof of personal use, and a prescription from a registered medical practitioner. If the enclosed documents are satisfactory, the CLA grants the license in Form MD-21.

POST – MARKET SURVELLIANCE OF MEDICAL DEVICES: (21)

The table 15 describes an overview on Materiovigilance Programme of India.

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Table 15: Overview of Materiovigilance Program of India

Programme Name	Materiovigilance Programme of India (MvPI)
Approved by	Ministry of Health and Family Welfare, Government of India.
National Coordinating Centre	Indian Pharmacopoeia Commission, Ghaziabad.
National Collaborating Centre	Sree Chitra Tirunal Institute for Medical Sciences and Technology, Department of Science and Technology, Thiruvananthapuram.
Technical Support and Resource Centre.	National Health System Resource Centre (NHSRC), New Delhi
Medical Device Adverse Event Monitoring Centers (MDMCs)	10 centers all over the country

II. RESULTS AND DISCUSSION:

On a brief analysis of new Medical Device rules-2017, it was found that there are some of the challenges that are to be focused for proper implementation and build strong regulatory basement for medical devices.

1. Lack of regulations for software incorporated medical devices and standalone medical device software.
2. Quality limits for medical devices.
3. Limited no. of Medical Device Testing Laboratories.
4. Price control of MD.
5. Sale of MD.
6. Advertisement of MD.

1.Lack of regulations for software incorporated medical devices and standalone medical device software.

IMDRF defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device".

SaMD should work to improve patient health by diagnosis, treatment and their health management. (27)

Categorization of SaMD as per IMDRF: (27)

Based on necessary principles, SaMD are summarized into 4 categories:

- **Category IV: (very high impact)**

SaMD used for diagnosis and treatment in a critical disease condition. E.g.: Diagnosis and identification of benign or malignant lesion

- **Category III: (high impact)**

SaMD used for diagnosis and treatment in a serious disease condition. SaMD used to drive clinical management of critical disease condition.

E.g.: Detection of interrupted breathing while sleeping by software associated smart microphone device.

- **Category II: (medium impact)**

SaMD used for diagnosis and treatment in a non-serious disease condition. SaMD used to drive clinical management of serious disease condition.

SaMD used to inform clinical management of critical disease condition. E.g.: Diagnosis of arrhythmia by analysing the heart rate

- **Category I: (low impact)**

SaMD used to drive clinical management of non-serious disease condition.

SaMD used to inform clinical management of serious or critical disease condition. E.g.: ECG rate determination SaMD.

So, hereby I can conclude that ―India should also implement regulations on software incorporated medical devices and standalone software‖.

2. Quality Limits on medical devices.

Similar to drugs,

Specification criteria for each category of the notified medical devise need to be included in the Indian Pharmacopoeia for national standard.

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3. Limited number of Medical Device testing laboratories

There are only 15 notified medical device testing laboratories in India. Since now as per the new Medical Device Rules-2017, there are approximately 350 medical devices and 250 in-vitro diagnostics. Where only 15 testing laboratories are not sufficient for such huge no. of devices.

4. Price Control on Medical Devices (9)

Though the medical devices are separated from the definition of drugs, the pricing of MD pricing is still controlled under the category of drugs.

Pricing of MD are controlled the DPCO, 2013 by NPPA under the ECA.

Similarly for medical devices, a draft NMDP, 2015 recommended the formation of NMDA for the price control on MD under the ECA.

The draft also suggests Government to announce regulations exclusively for controlling price for identified medical devices through a separate MDPCO Recommended constitution of NMDA,

- Chairperson
- Joint secretary
- Member secretary
- Two medical practitioners
- Two scientists or medical device technologists
- Secretary general of Quality Council of India (Ex-officio member)

5. Sale of Medical Devices:

According to new MDR-2017, the provisions on sale of medical devices, says that they follow 'Sale of drugs other than Homeopathic Medicines' regulations of the DCR, 1945.

But medical devices are simple medicines there are very complicated devices, hence a separate regulation should be published for the sale of medical devices.

6. Advertisement of medical devices: (28)

Direct-to-consumer advertisement is always a challenge for both devices and pharmaceutical companies in India. But there are lots of confusions in advertisement of medical devices on what rules to be followed because,

- DCA &DCR, says manufacturers are not allowed to advertise, does it mean importer or distributor can advertise?
- New Medical Device rules 2017, has no provision or restriction of device advertisement. Does it mean all manufacturers, importers or distributors can advertise?
- DMRA and DMRR, stays restriction on all individuals including manufacturer, importer and distribution CSRACI published by Advertising Standards Council of India, does not lay restriction on medicine or device advertisement, but says the information provided via advertisement should not be offensive or misleading to the user public.

All the above are Indian regulations pertaining to advertisement, but confused with what regulations to be followed.

So, Government should concentrate on updating the existing rules or provide new rules for the advertisement of medical devices.

The above are the some of the loopholes in the new Medical Device Rules and also suggest some of the recommendations to the same.

CONCLUSION:

The IMDI has evolved significantly in the past few decades. But it lacks in rules and regulations to control the medical devices.

In response to this the new Medical Device Rules-2017 was published by MOHFW, GOI which was effective from January, 01 2018.

The new rules have provided clarity on various aspects of medical devices, including:

- **Classification of medical devices**: This is based on the associated risk and intended use.
- **Single Window Clearance**: This is facilitated through the Online Medical Device Portal for submitting applications, granting permissions, licenses, and supplements.
- **Regulatory approval process**: This is well-defined for the manufacture, import, and clinical investigation of medical devices.
- **Perpetual license**: This allows for ongoing operation without the need for renewal.
- **Rationalized timelines**: This ensures efficient processing and approval times.
- **Provisions for change**: This includes changes in particulars and constitution.
- **Recall of medical devices**: This allows for the removal of defective or potentially harmful devices from the market.
- **Product standards**: These ensure the quality and safety of medical devices.
- **Inspection/Audit of manufacturing facility**: This ensures compliance with regulations and standards.
- **Quality Management System**: This ensures consistent quality of products and services.

- **Consolidation license**: This allows for the operation of multiple activities under a single license.

But the rules have not focused on certain areas, which are explained in Results and Discussion section and possible suggestions are also recommended.

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