Available online on 15 March 2019 at https://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Open Access to Pharmaceutical and Medical Research

Review Article

Open Access

Drug regulatory paradigm and challenges for Medical devices in India

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Abstract

The medical device industry in India has made speedy growth in the last few years but lag behind as compared to developed nations like USA, UK, etc. The government has taken the right step by separating the medical devices from general medicines from regulation viewpoint. Medical devices in India are governed by national drug regulatory agency, CDSCO (Central Drug Standard Control Organization) for quality and manufacturing standards. The CDSCO regulations are given to maintain the quality in manufacturing, packing and distribution of medical products. Each developed country has their own regulatory approval procedure and renewal requirements. The Indian government also adopted strict rules and regulations with respect to medical device and framed the new Medical Device Rules-2017. The medical device industry is principally import driven market close up to 75% and export up to 38% only. The national medical device policy2015 is driven out to strengthen the market of medical device and to reduce the burden on import of medical device (1). Recently NPPA capped the prices of medical devices such as coronary stents and knee implants under the DPCO (Drug Price Control Order). NPPA is the organization of government of INDIA which was established, to regulate the prices of controlled bulk drugs and formulations and in some extent medical devices. The NPPA have a mixed impact on Indian population and market, a large number of Indian population have received major benefits with respect to their healthcare costs (2, 3), at the same time major device manufacturer such as Abbott Healthcare , Medtronic filed the application to NPPA to increase the ceiling prices of their latest generation medical devices. As a negative impact, the MNCs withdraw their latest innovated products, affecting the quality of medical services, medical tourism, no investment in research and development of medical device etc.

Recommendations to government include: spending more percentage of GDP on healthcare, prioritizing the most important medical devices and provide them at subsidize price to government organization. The government should have more focus on production/manufacturing of medical devices indigenously under "Make in India" scheme.

Keywords: Medical Devices, CDSCO, WHO, NPPA, Price Regulation.

Article Info: Received 11 Feb. 2019; Review Completed 08 Mar. 2019; Accepted 12 Mar. 2019

Cite this article as:

Bansal A, Shukla V.K, Chauhan S, Yamini Kanti SP, Kumar S, katrolia A. Drug regulatory paradigm and challenges for Medical devices in India. International Journal of Drug Regulatory Affairs [Internet]. 15 Mar 2019 [cited 15 Mar 2019]; 7(1):25-33. Available from: http://ijdra.com/index.php/journal/article/view/299

DOI: 10.22270/ijdra.v7i1.299

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1. Introduction

According to WHO (World Health Organization) "Medical device" means any apparatus, instrument, appliance, machine, reagent for in vitro use, implant , material or other similar article, software, predetermined by the manufacturer to be used alone, or in combination for specific medical purpose for human beings for :

- Diagnosis, monitoring, treatment, prevention or alleviation of diseases,
- Supporting or sustaining life, disinfection of medical devices,
- Examination of specimens procure from human body,
- Investigation, support of anatomy and physiological process (4).
  - ➢ Note : motive of medical device is not achieved by immunological, pharmacological or metabolic means

1) Products which may be review to be a medical device in some purview but not in others encompass:
   - Disinfected substance
   - In- vitro fertilization devices
   - Aids for disabled persons
   - Animal /human tissue incorporating devices

Ministry of Health and Family Welfare (India) define medical device as:

"Active diagnostic medical device" means device used whether alone or in combination with any other medical device for diagnosing, monitoring, detecting, and treatment of any physiological condition, illness, state of health or congenital deformity.

"Active medical device" means a device, the working of which rely on a source of electrical energy or any additional source of energy other than the energy produced by human or animal body or gravity.

"Active therapeutic medical device" whether used alone or in combination with, to replace, modify, restore, or to support biological functions or structures for the treatment of any injury, illness or handicap (5).

Medical devices a billion dollar universal industry with sustained growth. With new innovations and advancement in technology medical device industry have huge and great opportunities, thus the national competent authorities are laying down and publishing the rules and guidelines for the approval process and market authorization of new evolving technologies. These regulations create challenges for manufacturer, innovator, importer and exporter to obtain approval in India. This review article imparts an outline and analysis of new "Medical Devices Rules 2017" released by MHFW (Ministry of Health and Family Welfare).

These new medical device rules published on 31st January 2017 and implemented from 1 January 2018.

India is among the top 20 markets of medical devices at global level and 4th largest at Asia level, valued at approximately $5.4 billion and this industry alone is expected to reach at $10.1 billion in 2020 having a compound growth rate of 11% annually between 2008 and 2015 with an approximate 10 year CAGR of 15% (6-8).

Currently India import 70% of their medical devices for their domestic use and only 38% of medical devices are exported that is manufactured in India. The new rules are well described and having a 360 degree focus to reduce import dependence and to uplift manufacturing potential and export competency(9).

Table 1 Old and New Medical Device rules

Parameters	Old medical device rules(6, 10-14)	New medical device rules 2017 (15, 16)
Market overview	• Unregulated market, Pose challenges for market approval • USFDA and CE (European Conformity) approved medical devices are allowed for approval. • No rules and regulations for devices, regulated as drug under drug and cosmetics act1940 and rules 1945.	• Highly regulated , ease in market approval Country has its own approval procedure. Manufacturer doesn't need foreign regulatory approval. • Separate medical devices rules published in 2017.
Regulatory	• Device classified under notified medical device into 15 categories. • No online e procedure • No list of defined /required documents, no audit, no renewal requirements, undefined approval procedure.	• Medical device classified on the basis of risk as A, B, C, D. • Online procedure for application and grant of license • Defined documents list, renewal requirements, audit of manufacturing facility
Registration and renewal	• No audit for manufacturing facility • Quality documents are not up to standard. • Duties of manufacturer, importer, exporter, distributor, auditor, drug inspector are not clearly defined or mentioned. • Approval and registration certificate is valid for only three years. • Form 40 – application form Form 41- registration certificate issued	• Audit required for manufacturing facility • Quality documents required to meet the new rules • Duties of manufacturer , importer, exporter , distributor , auditor and drug inspector are clearly defined • Approval and registration certificate is valid for five years. • Application form based on the type of medical device.
Import , export , manufacture , distribution and sale	• QMS (Quality Management System) is not covered. • CDSCO handled all the activities • No rules for license cancellation, or suspension • No such rules and provisions for the conduction of clinical trials of medical device.	• Quality management system is covered and obey the ISO 13485 • Import and clinical trials will be managed by CDSCO. Manufacturing will be managed by central licensing authority. • Separate rules and guidelines for the conduction of clinical trials for medical device.
Shelf life and labeling	• No such requirement	• New labeling guidelines are provided. • The shelf life should not exceed five years.

2. Classification of medical device under schedule M III

Classification on the basis of risk according to medical devices rules 2017 (6, 17).

Parameters for the classification of medical devices

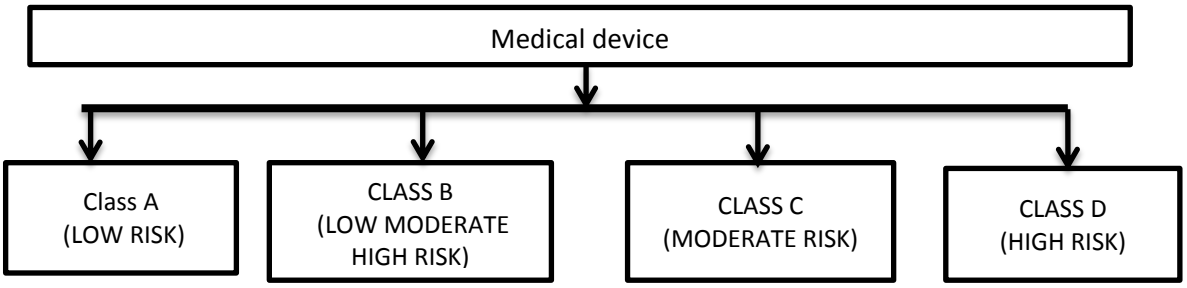

Figure 1. Parameters for the classification of medical devices on the basis of risk

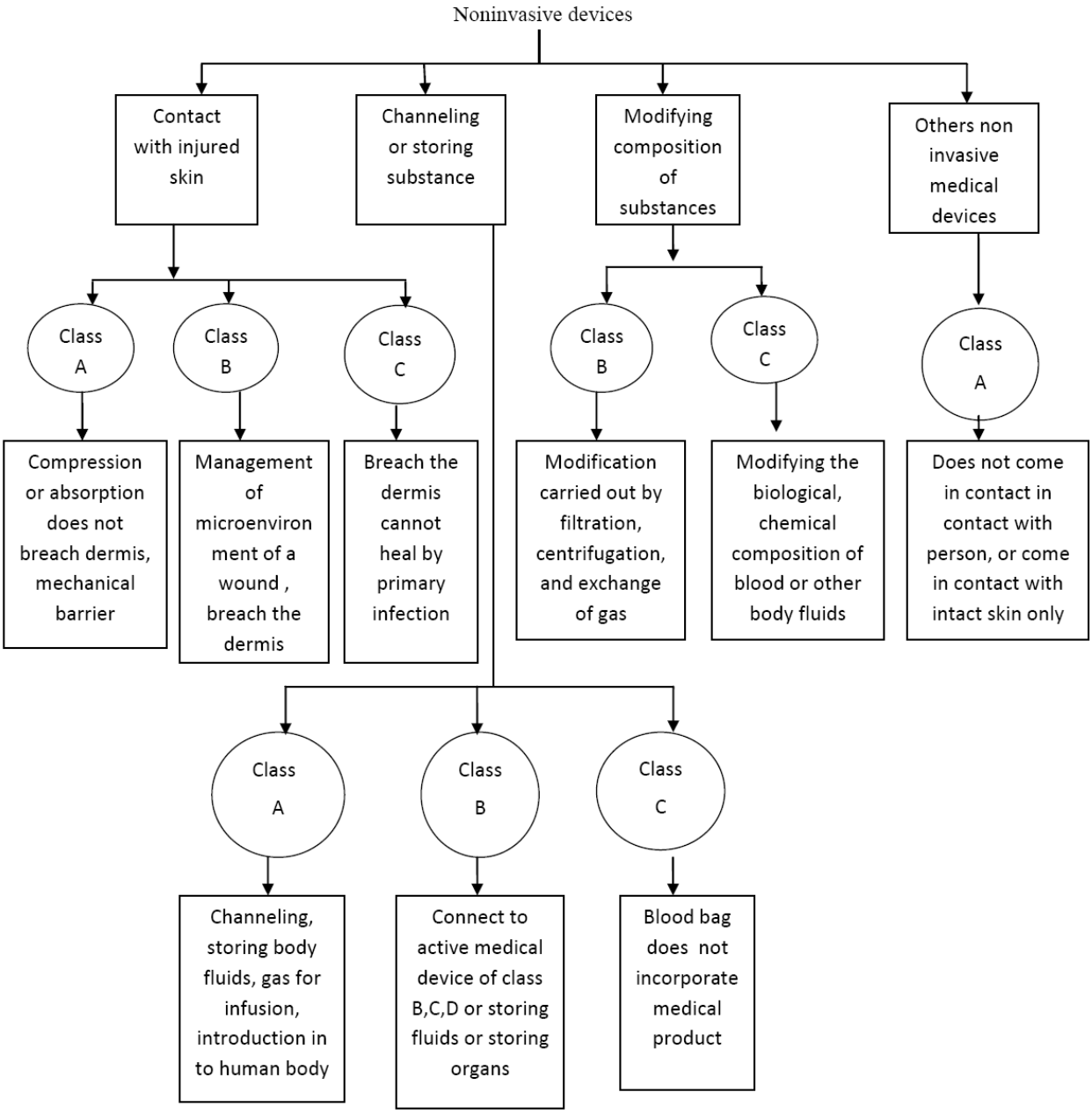

Figure 2. Classification of Noninvasive medical devices

Examples of devices according to classification based on risk:

Class A: Island dressings, wounds strips, gauze dressing, anesthesia, pressure indicator, syringes without needle, wound drainage devices, corrective glasses and frames, eye occlusions, conductive gels, pressure limiting devices.

Class B: Hydro gel dressings, refrigerators for storing blood, non-medicated impregnated gauge, medical device for filtration of blood, polymer film dressings.

Class C: Dressing for chronic ulcer wounds, dressings for severe wounds, haemodializers, blood bag, device incorporating to provide a temporary skin.

3. Parameters for classification of invasive medical device

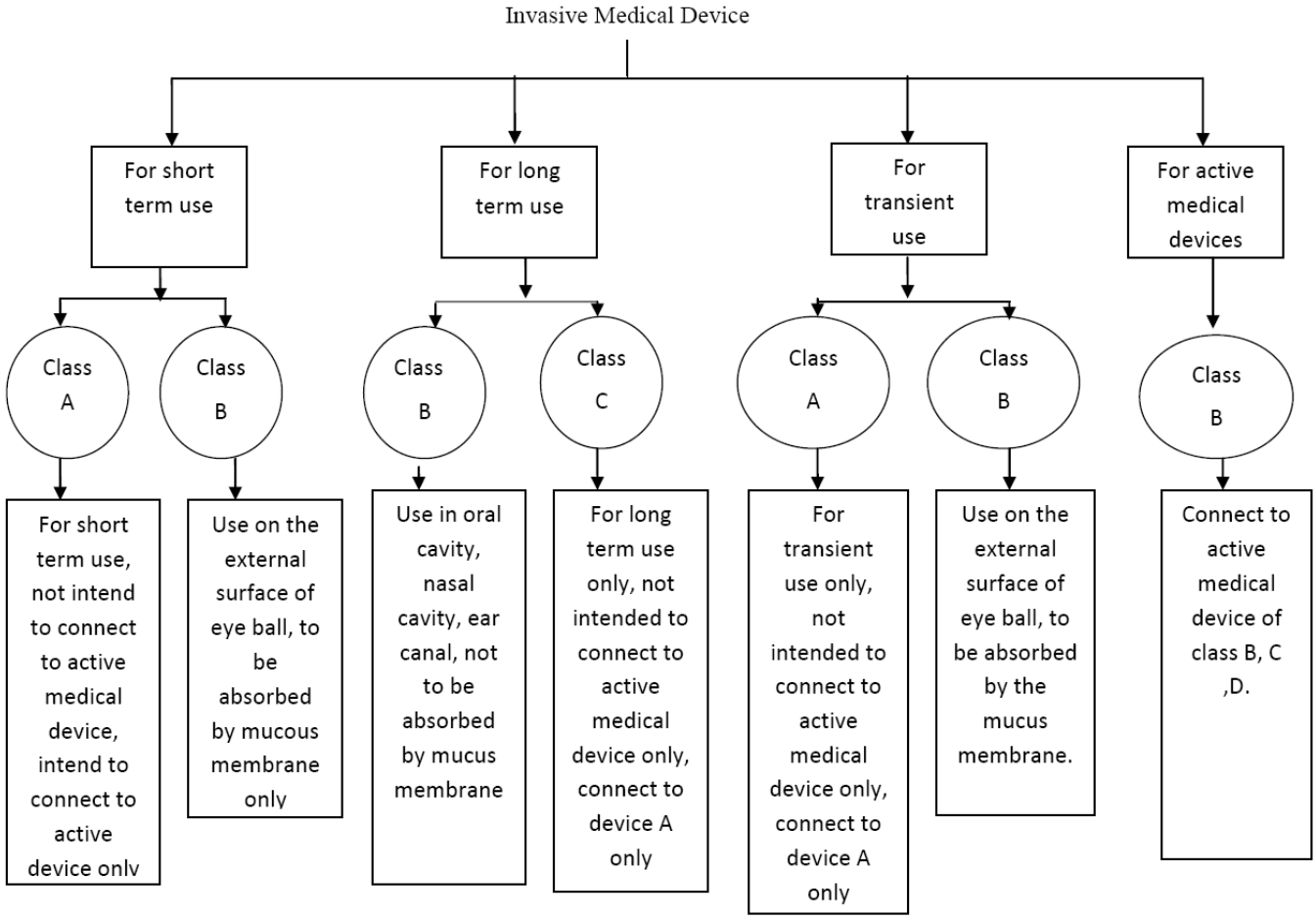

Figure 3. Classification of Invasive medical devices

Examples of invasive devices based on risk classification:

Class A: dental impression material, impression trays, examination gloves, dressings for nose bleed, tubes for pumping the stomach, enema devices, handheld mirrors used in dentistry,

Class B: tracheal tubes, orthodontic material, urinary catheters, removal dental prosthesis

Class C: long term and short term corrective contact lens, urinary catheters for short term and long term, tracheal tubes and stents and vaginal pessaries.

4. Parameters for classification of surgically invasive medical devices

Parameters for classification of surgically invasive medical devices is given in the figure 4.

Examples of surgical invasive devices based on risk classification:

Class A: surgical instruments

Class B: powered dermatomes, pulp testers, electrical acupuncture, eye electromagnets

Class C: Central nervous system instruments, and heart defects.

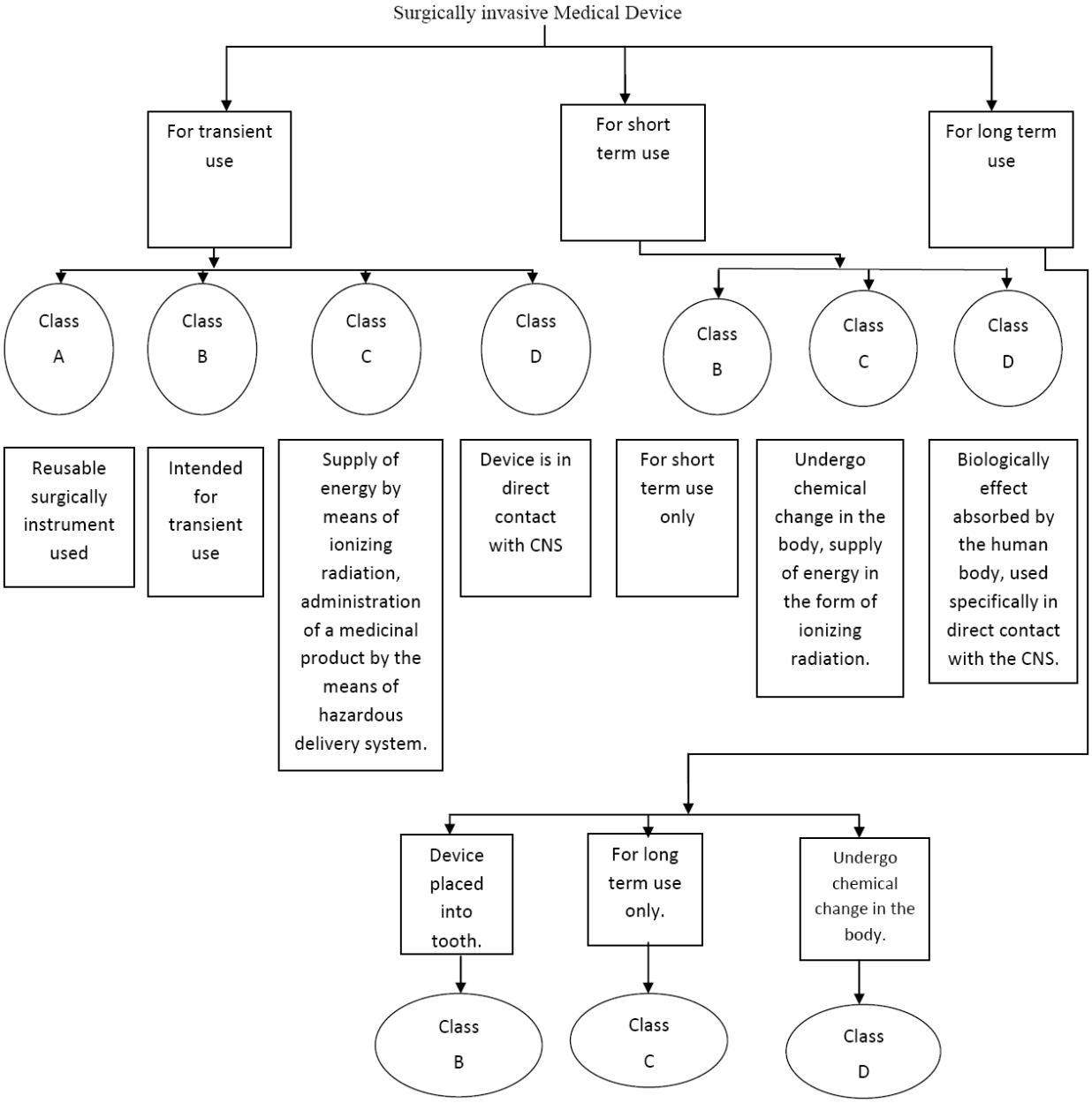

Figure 4. Classification of Surgically Invasive medical devices

5. Miscellaneous classification

Class A: Surgical instruments (reusable)
Class B: Electrical acupuncture, cryosurgery equipment, eye electromagnets, pulp testers.
Class C: Electrosurgical generators, kinetic energy, blood warmers
Class D: Central nervous system instruments (CNS), and heart defects

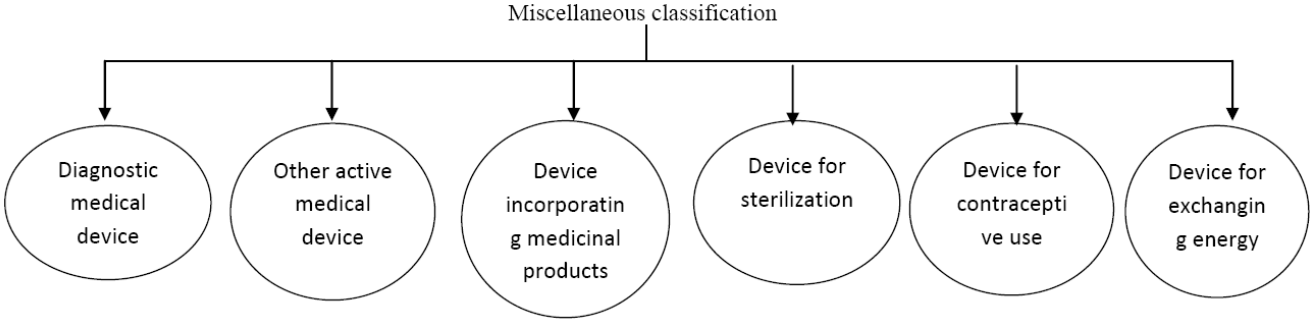

Figure 5. Miscellaneous Classification of medical devices

Table 2 Requirements for approval of Medical Devices (17-19).

Compliance for regulation	Class A	Class B	Class C	Class D
Quality management system	✓	✓	✓	✓
Electrical safety testing system	✓ *	✓ *	✓ *	✓ *
Report on risk analysis	✓	✓	✓	✓
Device master file		✓	✓	✓
Biocompatibility data		✓ **	✓ **	✓ **
Animal testing			✓ **	✓ **
Clinical data			✓ ***	✓ ***

* For electrical supply based devices
** For invasive or implantable devices
*** For investigational devices

6. Regulatory scenario and challenges (20, 21)

In India healthcare business is a major investment which is expanding with the increase in population and higher expectation. Medical device market is increasing crossing all the barriers that occur due to lack of quality standards, regulations or relatively less per capital expenditure on health sector. The market is presumed to be growing about 8% annually. On 31st January 2017 ministry of health and family welfare published the "new medical device rules" which come into effect from 1st January 2018. Under the "make in India "project there is the need to raise the global competitiveness in the manufacturing and healthcare industry.

1. October 2014 , formation of task force
   The department of pharmaceutics made a task force to find out the issues relating to development of domestic production.
   ⇩
2. September 2014 , Make in India
   Prime minister of India publicizes the Make in India campaign focus on various sector including medical devices.
   ⇩
3. December 2014 , 100% FDI in medical device
   Introducing 100% FDI in medical device sector provide opportunities for invention and innovation
   ⇩
4. April 2015 , medical device parks
   Established in four major states, to reduce import and to create manufacturing environment.
   ⇩
5. January 2016 , duty structure
   Elimination of additional custom duty and significant increase in import duty to promote domestic manufacturing.
   ⇩
6. January 2017 , medical device rules
   Ministry of health and family welfare published the rules for medical device rules and laid down the classification on the basis of risk

Challenges face by medical device industry (22, 23)

1. High import dependency
2. Lack of technology and innovation
3. Lack of research and development fund
4. Talent deficiency and lack of focus in maintaining healthcare ecosystem
5. Inadequate regulatory standard and lack of quality standard
6. Inadequate healthcare system: uneven population distribution, 69% Indian population lives in rural areas and 73% qualified doctors live in urban areas.
7. The basic custom duty for the import of medical devices is zero while they charged 7.5% basic custom duty on the import of component of medical device used by the domestic manufacturer to manufacturer the medical device. The government starts" Make in India" project but its own policies are destructive to Make in India and favor the import of medical device. So it's the time for the government to correct its inverted duty structure policy to enhance the domestic manufacturing.
8. The industry wants a separate medical act and a regulatory body covering the scope of Medical Device Rules and ensure better quality standards at global level.

Recommendations to government (20, 24)

- Software and standalone documents are not included in the new rule.
- Safety and quality guidelines are (lower and upper limits) are missing.
- Enhance the team work between technological and medical universities.
- Provide training received by medical and Para-medical staff.
- Seminar and conference should be held on how to comply with foreign regulations.
- Increase quality standards regarding medical devices.
- Provide financial assistance to smaller medical device companies
- Medical device parks: These parks will have the facilities for testing and manufacturing of devices resulting in affordable and better products.
- Indigenous certification for quality standards:

- Preferential purchase policy: he purpose is to enhance the domestic manufacturing and give preference in purchasing domestic products.

Price regulation (3)

The government is harmonious in making healthcare more accessible and affordable to all its citizens. The pharmaceutical industry is under the control of NPPA (National Pharmaceutical Pricing Authority) and recently the medical device is under the lamp of government for price control.

NPPA comes under the ministry of chemical and fertilizers, Department of Pharmaceuticals (DOP). It is not a statutory body. Its aim is to supervise and fix the prices of bulk drug and formulations under DPCO (Drug price control order).the first medical device on which price capping has been done is coronary stents. The NPPA cut down the ceiling prices of coronary stents by nearly 75%. NPPA classify the stents mainly into two categories BMS (Bare Medical Stent) and DES (Drug Eluting Stent). The revised retail price of bare metal stent is INR 7,260 and DES (Drug Eluting Stent) is priced at INR 29,600.

Medical device (Stent) manufacturer such as Medtronic and Abbott vascular filled an application to raise the ceiling prices of their latest generation of medical devices. NPPA also notified 19 medical devices that are laid down in its monitoring list in May 2017. It is important to note that after the notification of price capping, manufacturer cannot withdraw the products from the market for a period of 12 months from the notification date and without notify the NPPA.

On august 2017, NPPA capped the prices and trade margins for knee implants.

Table 3 Different types of knee implants and Prize

Different types of knee implants	Old price	New price
Cobalt chromium knee implant	1,58,300	54,270
Flexible implant	1,80,000-4,50,000	76,600
Revision implant	2,75,000-6,00,000	1,13,950
Specialized implant	2,75,000-9,00,000	1,13,950

Healthcare economics

In India healthcare industry is managed by two participants: first is private sector (70%) and the second is public sector (30%). Hospitals put money heavily in infrastructure building, capital equipment, cost of land is higher than other countries and this makes healthcare industry unsustainable to deliver at low prices. Manufacturers also spend a lot of resources on research and development, training of medical device service providers which is not visible to consumers. India spend lower amount on healthcare of its GDP unlike other large economies. Price Capping may not be the effective solution for health services in India.

Procedure price cap (20)

The state of west Bengal published and updated the west Bengal clinical establishment act, 2017. Its main purpose is to bring the transparency and to stop the medical negligence in private hospitals and nursing homes. This act is patient friendly. The important features of the act include: treat the accidental patient without the payment of fees, another step is capping of package rates for intensive charges, consultation, investigation, implants. Further no extra charges will be taken for additional treatment, if provided to patient. The prices of package is not been introduced till but if introduced may usher to an evacuation of private investment from the state (25). However similar legislation is introduced by the Karnataka government termed as "Karnataka private medical establishment bill, 2017, however it is kept dormant due to the protest from the medical community (26).

The central and state government needs to come together and adopt a comprehensive approach to raise affordability and to reduce cost. One of the method to achieve this is "NITI aayog" should come in front and first prepare a model for "clinical establishment bill" and be introduced in parliament then adopted by all the member states.

Developed countries have robust health insurance framework that provide majority of healthcare benefits and finance a large part of hospital care costs.

Table 4 Different Payment mode

Parameters	Developed countries	India
Product based payment	Shared billing between insurance companies and government	Major portion by self-pocket expenses , also depend upon public private hospitals and shared billing by insurance companies
Package rates	Fixed procedure fee depend upon diagnosis , treatment system	Procedure fee is not fixed; depend upon hospital, quality region.
Device price capping	Capping at healthcare providers fees and covered in package rates	Initiate the price capping at device fee such as stents , implants

Effects of price capping (20)

- Device manufacturer multinational companies like Abbott and Medtronic who brings new technology,

invest heavily in research and development of medical device, end up with extract out their latest generation products from the market due to price capping do not make them commercially viable.
- There will be a significant effect on medical tourism as foreign patients looking for high quality health services will not come to India for treatment whereas Indian patient travel to neighboring countries for newer generation products.
- MNCs are not conducting seminar, conferences, training on latest generation products due to the reason that they are no longer to sell their products, their profit margins are not enough for these sessions.
- Due to severe decrease in profits for medical device manufacturer lead to rise in the prices of that product that do not fall under the price caps.

Although healthcare providers do not ignore India due to its big market. They pursue to sell their generic devices only, not the latest products thus affect the quality of care.

Recommendations by author

- Allow the MTAB (Medical Technology Advisory Board) to recognize the procedure and priority medical device that reveal the need from diseases burden.
- India lags behind other developed countries in term of healthcare spending as a percentage of GDP.
- Like other developed countries bundled payment models should be made to line up the incentives for private hospitals.
- Supply of divergent stents at minimal or subsidized prices to governmental agencies or hospitals for use with underprivileged sections.

Discussion

Following review of the Medical Devices Rules, 2017, it is apparent there are significant differences between the old and new regulations for medical devices. The Medical Devices Rules, 2017 have many more requirements than the previous edition, such as quality management system, application of regulatory standards, proper manufacture licensing requirements, shelf life restrictions, more focused clinical regulations and risk based classification system.

The government ought to support and encourage local manufacturing through some incentives and infrastructure along with the price regulation as the Indian medical device sector is highly import driven. In the intervening time, the Health Ministry should keep a check on the quality of raw materials used in the manufacturing of devices so that the Indian branded products gain maximum profit in International markets.

The Ministry of Consumer affairs, as well as the Ministry of Finance, needs to consider some steps to control the retail price increment because of the tax structure. Because of the duties levied on these devices as well as on raw materials for their manufacturing, prices of them are touching sky high. The Government capped the price of some devices will provide relief from thousands to lakhs of patients, but it is just a single step towards the biggest milestone of creating an independent medical device regulator in India, which is yet to accomplish. The government is leaving no stones unturned to accomplish this task. Recently, the central government announced its plan to set up the India's first medical device park in Gujarat to complement "Make in India" drive. This park will create a base, which will then build up the element ecosystem and greatly improve the domestic production of the high-end medical device. National Institute of Pharmaceutical Education and Research (NIPER) will be the nodal institute for all research and development in that industrial park.

Affordability, access, and return on innovation are the three pillars of medical device industry, which should be balanced to get fruitful result. Obviously, the situation is very different now than it was 10 years prior. Sufficient resources are present to open the right doors of opportunities and present India as a global hub for innovation and technology.

7. Conclusion

The rules and regulation of medical devices around the world is very diverse. Medical device market is expanding very fast and India shows immense growth in this market. National drug authority is taking necessary steps to boost or enhance Indian medical device market. The new medical device fills the legislative void for medical device products due to unavailability of medical device rules and regulations. Time to time audit should be done to increase the quality standards. New rule have short timeline for new medical device products, attract investors around the globe because of organized rules and regulations. While make in India is an applaudable initiative, it would be worth for the government to unite it with many experts for make well in India campaign

Acknowledgments

The author is thankful to Dr. Vikesh Kumar Shukla and Ms. Shikha Chauhan, Assistant Professor, Amity Institute of Pharmacy, Amity University, Noida, Uttar Pradesh, India for providing guidance, facilities and encouragement to carry out the work.

Conflict of interest

The authors declare that there is no conflict of interest.

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