CONDUCIVE ENVIROMENT FOR FOSTERING INDIA SPECIFIC INNOVATION: NEW MEDICAL DEVICE RULES 2017

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REVIEW ARTICLE

Chauhan Pratibha*, Chauhan Rahul

Reckitt Benckiser (India) Pvt. Ltd., India.

**Corresponding Author's E-mail: pc88pharma@gmail.com*

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ABSTRACT

The medical technology sector in India valued at approximately $ 10 billion in 2015 at end consumer prices and is growing at 10-12 percent annually. Currently, the Indian medical devices industry represents just over 2 percent of the global medical device market. With such immense potential, some of the challenges that this industry faced with lack of framework. India's medical device sector was greeted by a breakthrough announcement during union budget speech in 2017. India's finance minister declared that the government would formulate new norms, 'harmonized with international rules', for the medical devices sector. Post which Ministry of Health and Family Welfare released a media statement that it had notified the Medical Device Rules 2017 on Jan 31st, which would be enforceable from January 2018. These new medical device rules would attract more foreign investment and reduce prices of medical devices. This positive policy push for the development of the domestic medical device market will potentially bring more devices under its ambit, the new medical rules will bring in a huge wave of relief to consumers, protecting their right to access high quality and safe products. As the fastest growing healthcare market in the world, the government can further take several measures to create a conducive environment to consolidate the growth of the medical devices sector with regularly advising new guidances. The recent notification on essential principles for safety and performance of medical device, risk based classification with list of medical devices and in-vitro diagnostics, notified bodies auditing the firms demonstrates the favorable environment for manufacturing of medical devices nurturing growth and innovation in the country.

Keywords: Medical devices, Essential Principle, Risk Based Classification, Policy infrastructure, Regulatory regime.

INTRODUCTION

The Primer

At present, the global medical technology market is around $ 350 billion, which is expected to grow 5 percent annually for next 5-7 years. The Indian market is among the top twenty in the world by market size, and fourth in Asia after Japan, China & South Korea. (1)

The Indian medical devices industry has huge potential to grow and be among the top 5 medical devices manufacturing hubs globally. It can also significantly contribute to GDP of the country that will result in fulfilling the government's vision of healthy India. The current medical device industry is driven by innovation and new technologies. The advent of engineering innovations has led to the recent development of low cost products that are at par with existing products on quality. (1)

Availability of advanced and sophisticated medical technology is creating new markets & applications, increasing the dependence by doctors on advanced medical devices. This is leading to rapid obsolescence of existing medical technology thereby creating demand for replacement & upgradation of products. (1)

Medical devices vary according to their intended use and indications. Examples range from simple devices such as tongue depressors, medical thermometers, and disposable gloves to advanced devices such as computers which assist in the conduct of medical testing, implants, and prostheses. The design of medical devices constitutes a major segment of the field of mechanical engineering. (2)

The regulatory authorities recognize different classes of medical devices based on their design complexity, their use characteristics, and their potential for harm if misused. Each country or region defines these categories in different ways. The authorities also recognize that some devices are provided in combination with drugs, and regulation of these combination products takes this factor into consideration. (2)

In current system, India relies on imports to supply its healthcare system with medical technology. The medical tourism and luxury healthcare markets are among India's fastest-growing industries, which create significant demand for specialized, high-tech medical equipment. There is consistent demand for surgical instruments, cancer diagnostics, orthopedic and prosthetic equipment, imaging, orthodontic and dental implants, and electro medical equipment.(3)

Task Force

As a part of the endeavor to boost growth in the medical device sector, a task force was constituted under the chairmanship of the secretary, Department of Pharmaceuticals (DoP). The prime objective of the task force was to address issues related to the promotion of domestic production of medical devices.

The task force reviewed the industry from the following perspectives:

- Sector Overview
- Policy and Infrastructure
- Regulatory Environment

This task force studied and analyzed the sector in detail and sourced comments from stakeholders as well. It recommended a host of policy, infrastructural and regulatory measures. The report released in April 2015, talks about the envisioned ecosystem for the medical device.

The task force has acknowledged the need for infrastructural development and an appropriate mechanism for efficacy and safety testing is necessary to achieve growth. The recommendations aim at complete ecosystem to support medical device sector in India.

The recommendations covered policy support, infrastructure, validation center, skill development, R&D, pricing policy, duty structure, regulatory framework which can be further studied in detail. (4)

REGULATORY AND POLICY FRAMEWORK

The medical device sector has witnessed consistent growth over the last six years (from USD 3.1 billion in 2009 to USD 5 billion in 2015). However, factors such as inadequate regulatory systems, non-alignment with global standards and the lack of quality product testing infrastructure are the issues that hinder its progress. (4)

Current Regulatory Regime

The existing regulatory framework for medical devices in India has been inadequate for a USD-4.9 billion industry. Currently, only 14 devices are notified as medical devices and have specific regulations. Other medical devices are treated as 'drugs' under Drugs and Cosmetics Act, 1940 & Rules. As a result, the remaining medical devices have been subject to the restrictive code/laws of pharmaceutical sector. Ambiguity in the clinical trial mechanism and lack of specific regulatory framework to govern the manufacturing standards and quality control systems have resulted in a lag in product quality as compared to global standards.(4)

Proposed Regulatory Establishment

The new Rules have been framed in conformity with Global Harmonization Task Force (GHTF) framework and conform to best international practices. The new Rules seek to remove regulatory bottlenecks to make in India, facilitate ease of doing business while ensuring availability of better medical devices for patient care and safety.(5)

The general classification of medical devices are as follows:

- General Devices (other than invitro diagnostic medical devices)

- Invitro diagnostic medical devices

The rules classified as per GHTF practice, are classified further basis associated risk wherein

the manufacturers of medical devices will be required to meet risk proportionate regulatory requirements that have been specified in the Rules and are based on best international practices.

Table 1: Risk Classification of Medical Devices

Risk Classification of Medical Devices	
Risk	**Class**
Low Risk	A
Low Moderate Risk	B
Moderate High Risk	C
High Risk	D

Schedules:

The rules further defines the schedules, chapters, forms, fees etc. in view of the international standards of guidance and ease of business.

Table 2: Medical Devices Schedules & their Inclusion

Schedules	Inclusions		
First Schedule	Classification of medical devices and in vitro diagnostic medical devices		
	Part I	Classification of medical devices other than in vitro diagnostic medical devices	
	Part II	Risk classification provisions for in vitro diagnostic medical devices	
Second Schedule	Fee payable for licence, permission and registration certificate		
Third Schedule	Documents to be submitted for registration of Notified Body, its duties and functions		
	Part I	Documents to be furnished along with application	
	Part II	Duties and functions of Notified Body	
Fourth Schedule	Documents required for grant of manufacturing and import licence		
	Part I	POWER OF ATTORNEY (Only for import)	
	Part II	(i)	Information to be submitted with the application for grant of licence to manufacture or import of a Class A medical device
		(ii)	Information to be submitted with the application for grant of licence to manufacture or import of a Class B, Class C or Class D medical device
	Part III	Appendix I	contents of a site or plant master file
		Appendix II	Device master file for medical devices other than in vitro diagnostic medical Devices
		Appendix III	Device Master File For In Vitro Diagnostic Medical Devices
	Part IV	Information required to be submitted with the Application Form for import or manufacture of medical devices which does not has predicate device	
Fifth Schedule	Quality Management System for notified medical devices and in vitro diagnostics		
Sixth Schedule	Post approval major and minor changes		
Seventh Schedule	Requirements for permission to conduct clinical investigation of medical devices other than in vitro diagnostics medical device which does not have a predicate device		
Eighth Schedule	Exemptions		

Chapters

The rules comprises of eleven chapters which are as follows:

Table 3: Medical Devices chapters & their Inclusion

Chapters	Inclusions
Chapter I	General Definition
Chapter II	Regulation of medical device
Chapter III	Authorities, officers and bodies
Chapter IV	Manufacture of medical devices for sale or for distribution
Chapter V	Import of medical devices
Chapter VI	Labelling of medical devices
Chapter VII	Clinical investigation of medical device and clinical performance evaluation of new in vitro diagnostic medical device
Chapter VIII	Permission to import or manufacture medical device which does not have predicate medical device
Chapter IX	Duties and powers of medical device officer, medical device testing officer and notified body
Chapter X	Sale of medical devices
Chapter XI	Miscellaneous includes - exemption from provisions related to medical devices, export of medical devices, rejection of application of license, debarment, mode of payment of fee and overriding effect.

Forms

The new rules comprises of around 40 forms some of which are captured here:

Table 4: Medical Devices: Type of License, Application & their Grant

Forms		
Purpose (Type of License)	**Application**	**Grant**
Certificate of Registration of a Notified Body	MD1	MD2
Licence to Manufacture for Sale and Distribution of Class A or Class B medical device	MD3	MD5
Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device	MD4	MD6
Licence to Manufacture for Sale and Distribution of Class C or Class D medical device	MD7	MD9
Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device	MD8	MD10
Form in which Audit or Inspection book shall be maintained	MD11	NA
Manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training	MD12	MD13
Issue of import license to import medical device	MD14	MD15
Import medical device for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training	MD16	MD17

Import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients	MD18	MD19
Permission to import small quantity of medical devices for personal use	MD20	MD21
Permission to conduct clinical investigation of an investigational medical device	MD22	MD23
Permission to conduct clinical performance evaluation of new *in vitro* diagnostic medical device	MD24	MD25
Permission to import/manufacture for sale or for distribution of medical device which does not have predicate medical device	MD26	MD27
Permission to import/manufacture for sale or for distribution of new *in vitro* diagnostic medical device	MD28	MD29
Additional Forms		
Memorandum to the Central Medical Device Testing Laboratory	MD30	
Certificate of test or evaluation by the Central Medical Device Testing Laboratory	MD31	
Report of Test or Evaluation of Medical Devices by Medical Device Testing Officer	MD32	
Application form a purchaser for test or evaluation of a Medical Device under section 26 of the Drugs and Cosmetics Act, 1940 (23 of 1940)	MD33	
Order under clause (c) of sub-section (1) of the section of Drugs and Cosmetics Act, 1940, (23 of 1940) requiring a person not to dispose of stock in his possession	MD34	
Receipt of stock of medical device for record, register, document or material object seized under clause (c) or clause (cc) of sub-section (1) of section 22 of the Drugs and Cosmetics Act (23 of 1940)	MD35	
Intimation of Person from whom sample is taken	MD36	
Receipt for Sample of medical device(s) taken where fair prices tendered thereof under sub-section (1) of Section 23 of the Drugs and Cosmetics Act, 1940 is refused	MD37	
Memorandum to Medical Device Testing Officer	MD38	
Registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical devices on behalf of manufacturer	MD39	MD40

A system of 'Third Party Conformity Assessment and Certification' through Notified Bodies is envisaged with a view to bring competency and effectiveness. The Notified Bodies will be accredited by the National Accreditation Board for Certification Bodies (NABCB). The NABCB will, before accrediting Notified Bodies, assess their competence in terms of required human resources and other requirements. These Bodies will undertake verification and assessment of Quality Management System of Medical Device Manufacturers of Class A and Class B category and may, on as required basis, be called upon to render assistance for regulation of Class C and D medical devices also.

The Rules also seek to evolve a culture of self-compliance by manufacturers of medical

devices and, accordingly, the manufacturing licenses for Class A medical devices will be granted without prior audit of manufacturing site. The manufacturer will, in such a case, be required to do self-certification of compliance with the requirements and based on such certification, the licence will be issued. However, post approval audit of manufacturing site will be carried out by the Notified Bodies to check conformance with Quality Management System in accordance to applicable standards as per Bureau of Indian standards. Foreign manufacturing sites may be subject to inspection by notified bodies or central licensing authority. In the event of inspection requested, applicant is subject to pay inspection fee as notified in GSR 78(E). (6)

Manufacturer of Class A and Class B medical devices will be licensed by State Licensing Authorities concerned after Quality Management System audit by an accredited Notified Body. For all manufacturing sites, Quality Management System will need to be aligned with ISO 13485.

Manufacture of Class C and Class D medical devices will be regulated by the Central Licensing Authority and, where required, assistance of experts or notified bodies will be taken. Import of all medical devices will continue to be regulated by CDSCO. A network of NABL accredited laboratories will be set up both, by the Government and by other entities, for testing medical devices. (5)

ENACTMENT

For now, the new medical device rules will cover only those devices which already fall under vision of CDSCO wherein companies with devices currently registered for sale in India can anticipate a transition period to comply with the new published rules following their 2018 implementation. The current list of devices with risk-classification also applies only to currently medical devices. By 2020, medical devices that are approved for import, sale and distribution in India must bear unique identifiers which will be device identifies and production identifiers. The device identifier is a global trade item number and the production identifier is the device's serial number, lot/batch number, software version, and/or manufacturing and/or expiration date.

CONCLUSION

With new medical device rules which introduces more formalized registration requirement compared to country's current system including risk-based classification, unique identification and manufacturing quality audits by notified bodies will foster growth of this sector in the country at a faster pace with innovation in-hand.

Medical Devices sector has emerged as a focus sector in Make in India aspirations of the country. It has a tremendous potential to grow with a huge demographic dividend on demand side and India's research and development innovation capabilities on the supply side. The measures to lift current restrictions on shelf life of medical devices are much needed to appreciate the usability of device and establish trust in manufacturer quality systems, these are imperatives to strengthen ease of doing business.(7)

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CONFLICTS OF INTEREST

The content and views in article is author independent opinion and in no way related to Reckitt Benckiser's views and policies.

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