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Review Article

Regulation for Medical Devices in India

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ABSTRACT

In the era of competitive use of medical devices, stringent regulatory standards should be followed to ensure that the devices are safe, well studied and have minimum adverse reactions. Recently introduced guidelines and the amendment in the law will provide adequate guidance for both the manufacturers and competent authorities to manage cases efficiently and appropriately. India has emerged as one of the leaders in pharmaceutical sector. Like many other amendments in Drugs and Cosmetics Act that have boosted the global confidence in pharmaceutical sector in India, guidelines for devices will encourage the much needed research for devices in medical field. Pharmacy personnel can certainly play an important role in the regulation of medical devices. Safety, risks, effectiveness and performance of the medical devices need to be well established and regulated properly. It is necessary that the guidelines should be implemented and regulated effectively for a productive outcome to upgrade the health status of individuals.

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INTRODUCTION

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. Medical devices are helpful for the purpose of:

1. Diagnosis, prevention, monitoring, treatment or alleviation of disease.
2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
3. Investigation, replacement or modification of the anatomy or of a physiological process.
4. Control of conception

This includes devices that do not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means [1].

Significance of Medical Devices

The era of newer development and technology has decreased the morbidity and mortality of life. The medical development in terms of drugs and devices has brought

about the considerable change in the life of the individual (as offered by the cosmetic treatment, dentist, face and cardiology devices). Medical devices have improved the ability of physicians to effectively diagnose and provide the treatment for diseases, thus making great contributions to health and quality of life.

According to World Health Organization under Medical Device Regulations, the term "medical devices" includes everything from highly sophisticated computerized medical equipment down to simple wooden tongue depressors. The intended primary mode of action of a medical device on the human body, in contrast with that of medicinal products, is not metabolic, immunological or pharmacological. Medical devices include a wide range of products such as medical gloves, bandages, syringes, condoms, contact lenses, disinfectants, X-ray equipment, surgical lasers, pacemakers, dialysis equipment, baby incubators and heart valves. Medical device means any instrument, apparatus, implant, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related articles, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes like diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury; investigation, replacement, modification or support of the anatomy or of a physiological process; supporting or sustaining life; control of conception; disinfection of medical devices and providing information for medical

purposes by means of *in vitro* examination of specimens derived from the human body.

Medical devices have covered a major part of modern medical care. They are in many cases associated with improved quality of care but simultaneously associated with many problems. The approach to quality of devices has depended largely on regulation. According to global statistics, USA, Japan and European Union countries play a major role in the manufacturing of medical devices covering approximately up to 85% of the entire business. This being the major reason why it is the matter of concerns to the American and European regulation systems.

Like medicines and other health technologies, these are essential for patient care at the bedside, at the rural health clinics and at the large, specialized hospitals. Medical devices also add to the financial burden on the Government health sector. There market is showing an ever increasing double-digit growth. The cardiac devices alone are growing at the rate of 20 per cent. In India, the growth of the market is estimated to be between 10-15 per cent. It is a clear indication that the penetration levels are increasing in the country at a considerable rate. This is because of easy affordability by patients, increased awareness on health care and better input on hospital infrastructure.

The public believe that medical devices meet the highest safety standards. Realizing the importance of Pharmacovigilance, Ministry of Health and Family Welfare, Government of India, with WHO funding, initiated a country wide National Pharmacovigilance Program. Central Drugs Standard Control Organization (CDSCO), New Delhi, coordinates the program. The Honorable Minister of Health, Dr. Anbumani Ramadass at New Delhi, officially launched the program on November 23, 2004. CDSCO has established 2 zonal centres, 5 regional centres and 28 peripheral centers all over India and still the development is ongoing rapidly in the sector of medical devices [2-3].

Classification of Medical Devices

Medical devices are designed to improve patient's health and in diagnosis, therapy or surgery which are monitored under strict regulations by the food and drug administration, FDA. Medical devices are classified broadly into three classes based upon the US classification system, which defines the amount of risk involved with the medical device and proper procedures that must be followed when using and manufacturing the device [4].

Class I

These are simple in design and possess little or no potential risk. Medical devices classified as type I must follow general FDA policy which includes registering the medical device, proper branding and labeling, proper manufacturing techniques and the FDA must be notified prior to marketing the device. The example under the Class-I include tongue depressors, elastic bandages, hand held dental instruments and examination gloves.

Class II

These are more complicated in design and pose minimum risk. Medical devices classified as type II must follow general policy and special labeling, mandatory performance standards and post market surveillance. The example falling into the Class II medical devices are X-ray machines, powered wheelchairs, infusion pumps and surgical & acupuncture needles.

Class III

These are highly complicated in design and have the strictest guidelines because they pose the maximum risk. Class III Medical Devices must follow Class I and Class II guidelines but must also be pre-market approved by the FDA and a scientific review of the medical device must be made prior to marketing. Class III medical devices support or sustain human lives therefore malfunction is absolutely unacceptable. The example in Class III includes implanted pacemakers, heart valves and implanted cerebral simulators.

Regulatory authorities around the world have classified them based on their safety requirements and standards of quality to be set. Several criteria are considered to evaluate the potential risk: degree of invasiveness, duration of contact, affected body system and local versus systemic effects. The classification of medical devices differs from country to country but the classification in Table 1 gives a comprehensive view of various classes of medical devices [5-15].

Regulation of Medical Devices

The approach to quality of devices depends largely on regulation. Additionally, there also exist many issues in the interface between the machine and the user or the patient that are largely untouched by device regulation, and are considered in quality assurance programs. As essential as device regulation is, it is not sufficient to assure quality. Education is particularly important in this area. Quality assurance programs need to be familiar with common problems with medical devices and how to approach them.

The regulation of medical devices has emerged as a vast and rapidly evolving field which is often complicated by legal technicalities. For instance, legal terms and their meanings are sometimes non-uniform even within one regulatory system. Optimum safety and performance is demanded during the entire life span of a medical device: the government, the manufacturer, the importer/vendor, the user and the public each has a specific and individual responsibility to play in this risk management.

In India, the Department of Health has nominal jurisdiction over medical devices, evident from the illegal re-processing and re-packaging of used syringes for re-sale and the availability of equipment that fails minimum safety and quality standards. Unsterilized implants could cause

infections and stents coated with immune-suppressant drugs are capable of impairing the body's immune system.

All devices carry a certain degree of risk therefore, (for classification purposes) the Global Harmonisation Task Force (GHTF) has identified potential causes of hazards that warrant consideration. These include degree of invasiveness, duration of contact, the body system affected, and local versus systemic effects. An invasive device is usually considered to have higher potential hazard than an equivalent non-invasive. Simultaneously, devices with long duration of contact are assigned higher classes of potential hazard or risk.

In 2004, the Mashelkar Committee called for the creation of a specific medical devices division within the Central Drugs Standard Control Organization to address the management, approval, certification and quality assurance of medical devices. In 2005, the Maharashtra Food and Drugs Administration directed manufacturers and importers to obtain a license from the Drug Controller of India (DCI) for all in-vivo devices, especially drug-coated stents. The FDA initiative followed reports that a leading hospital in Mumbai had used illegal stents on its patients.

In a nutshell, continued increasing investment in private sector infrastructure, coupled with growing healthcare funding from the government, have resulted in a steady increase in the market for medical equipment and supplies. Analysts estimate the market will continue to grow by an average of 4.7 per cent over the next few years, driven largely by health tourism and the size of the Indian middle class. The recent liberalization of trade and investment laws, together, with a growing commitment to national healthcare, makes India one of the most promising emerging markets for medical device manufacturers.

Regulation of Medical Devices in India

In India the major source of pharmaceutical regulations is the Drugs and Cosmetics Act 1940. This legislation applies to the whole of India and for all products whether imported or indigenous. The legislation is enforced by the office of the Drugs Controller General of India (DCGI). However, at the field level, enforcement is done by the individual state Governments through their Food and Drug Control Administration (FDCA). Matters of product approval standards, clinical trials introduction of new drugs, and import license for new drugs are handled by the DCGI. With the help of Indian Council of Medical Research, New Delhi the approvals for setting up manufacturing facilities and obtaining license to sell and stock drugs are provided by the State Government. However, a similarly regulatory body for the Medical Devices rules and regulations is yet to be established properly.

Role of pharmacist in regulation on use of devices

India has emerged as one of the leaders in pharmaceutical industry. The Indian Pharma sector is growing exponentially. Its value in 2004 was US\$ 6 billion which has increased to US\$ 10 billion at the end of year 2006. On

the manufacturing side there are 23 000 manufacturers (1.2% in formulation, the rest in bulk drugs), imports are 4% of total size of domestic market value US \$ 3 billion, and export is Rs.30 000 crores (2007-08) [16]. Indian drug prices are among the lowest in the world. India has recently being viewed as a place with great potential for clinical research. The pharmaceutical sector and especially the pharmacists have been playing a lead role in these directions. Medical device sector has so far not been even in the thought process of pharmaceutical sector. Pharmacy graduates or post-graduates are showing awareness regarding various medical devices used in hospitals. There are very few pharmaceutical companies that have taken a lead in medical devices (except syringes, medical gloves, bandages, condoms, contact lens, disinfectants, etc). Pharmacy personnel certainly play an important role in the regulation of medical devices.

Following are the steps needed to play a positive role in the reputation of medical devices through pharmacists [4].

- It is necessary to have proper understanding of medical device safety, risk involved, the degree of invasiveness, duration of contact, the body system affected, and local versus systemic effects.
- One should weigh the risks against the benefits to the patients compatible with a high level of protection of health and safety so that maximum benefit and minimum risk is ensured when a device is being used by doctor.
- Pharmacist should be actively involved in the regulation of effectiveness and performance of medical device. One has to provide clinically effective parameters through the manufacturer which are relative to the medical condition. Clinical effectiveness is a good indicator of device performance, which is closely linked to safety.
- Pharmacists should be involved in the documentary of standards containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose.
- One has to ensure that the prescriptive, design, performance, and management specifications meet the standards.
- Pharmacists can promote to establish voluntary standards by consensus from all interested parties (the stakeholders). The use of voluntary/consensus standards may be developed by experts with access to the vast resources available in the professional and industrial communities. Conformity to such standards can also be assessed by an accredited third party (such as a notified body in Europe), and thereby improve and update the standards. All these can make medical device standards effective and efficient tools for supporting health care, and provide to the manufacturers have the flexibility to choose appropriate standards or other means to demonstrate compliance with regulatory requirements.
- Many countries lack access to high-quality devices and equipments that are appropriate for their specific

epidemiological needs. This is particularly true in developing countries, where health technology assessments are rare and where little regulatory controls exist to prevent the import or use of substandard devices. With the vast majority of devices in developing countries being imported

and this may increase the risk and need to be considered lives at risk.

Table1: Classification of Medical Devices from Regulatory Aspects

Europe	US FDA	GHTF (Japan)	Examples of Medical Devices
Class I	Class I*	Class A	Non sterile items or sterile items with a low potential risk: surgical instruments, urine bags, stethoscope, examination gloves
Class IIa	Class II	Class B	Sterile items surgical gloves, urinary catheters, stomach tubes, needles, tracheal tubes, IV giving sets
Class IIb	Class II	Class C	Blood bags, condoms, non-absorbable sutures, anaesthesia machines
Class III	Class III	Class D	Absorbable sutures

*With or Without GMP

CONCLUSION

In the epoch of advanced research and development, technology may have both pros and cons for the lives of human beings. Hence, a proper and stringent rules and regulations are required to be put forth in the practice. Number of regulatory bodies exist which are responsible for regulation and monitoring of the activities undergoing in terms of both socio-economic protection of human beings. Looking to scope and requirement of medical devices, India needs to enter in the global market at a larger level to manufacture their own devices. Thus, a proper rules and regulations are needed to encourage the efficient growth of device industry in India. Since, the world market is seeing the accentuating use of medical devices in varied type of patients and with unique patterns of disease, this will not only give a public safety assurance but also the manufacturer will get a detailed, accurate, long term surveillance of the medical device, generating more information and hints for further improvements. Education is particularly important in this area. Quality assurance programs need to be familiar with common problems with medical devices and how to approach them.

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