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REGULATION QUAGMIRE, INCLUSIVE INNOVATIONS AND ARRESTED DEVELOPMENT: EVIDENCE FROM THE INDIAN MEDICAL DEVICE INDUSTRY

Dinar Kale
Dinar.kale@open.ac.uk
Innogen institute, The Open University

ABSTRACT

In any healthcare sector, the medical device industry plays an important role in reducing overall healthcare costs and ensuring effective access to healthcare. However, in developing countries such as India compared to the success of the pharmaceutical and biotechnology industry, the medical device industry has not witnessed similar growth. In this context this paper studies factors and issues that hampered development of the medical device industry in India. Specifically it explores the link between regulatory policies and their impact on innovation and technology capability development in the Indian medical device industry. Further it examines the complex relationship between healthcare regulation, innovation, and sustainable development within the context of an increasingly globalising economy. It shows crucial role of smart and appropriate regulation in creation of the basic technological capabilities, incentivising inclusive innovation and affordable healthcare.

Keywords: healthcare, medical devices, India, regulation, development

1. INTRODUCTION

In the developing country context science and technology policies plays an important role in facilitating or inhibiting growth of a particular sector, industry or market. In healthcare sectors role of these policies acquired even more dominant role due to strong linkages between science and technology policies in creating human and infrastructural resources for the healthcare industries. In case of healthcare industries significant part of technology policies is concerned with devising regulatory policies that can ensure development of safe and effective products, therapies and services for all the populations. Indeed, as a result of the transformation and intensification of risks, to individuals and societies, that are widely associated with the bioeconomy, the regulation of healthcare sectors has become extremely important.

Given importance of healthcare costs and its role in ensuring affordable healthcare for all, it is almost impossible to overstate the importance of, or the importance being attached to, the healthcare sectors in the modern era. Unsurprisingly, the form, scope, and stringency of regulation have been, and continue to be, much discussed, with governments frequently oscillating between tight regulation and deregulation. The risk-driven inclination in the healthcare sector has been to regulate, and to regulate heavily.

A common response to control and direct innovative activities and products in the healthcare sectors is to draft statutory instruments, guidelines or codes. These regulatory efforts have tended to fragment and complicate innovation systems and product pathways, for which they have been loudly criticised. Ultimately, the dominant view that has emerged is that regulation hampers innovation and the development of strong and competitive industries or sectors. The studies of regulation in healthcare industries clearly points out its impact on shaping innovation, influencing industry structure and determining firm level technology strategies. While this can certainly be the case, this paper argue that an absence of regulation can be just as damaging to innovation within, or indeed the survival of, a field of inquiry or production. Based on the study of the Indian medical devices sector, this paper argue that regulation can have many salutary effects, some of them surprising, so neglecting to regulate, or deregulating where frameworks already exist, is not necessarily the way forward. This fact may not always be appreciated in jurisdictions with sophisticated legislative and regulatory infrastructures containing strong participative mechanisms.

Over the last decade the Indian pharmaceutical and biotechnology industries has emerged as a leading supplier of generic drugs and vaccines to both developing and developed countries, while India still imports more than 75% medical devices from advanced countries. The Indian pharma and biotech sectors are categorised as pioneers for developing inclusive innovations that ensured accessibility of affordable drugs and vaccines to majority of populations in the developing countries. In medical device industries some India firms are involved in developing inclusive innovations but struggling to receive market acceptability due to ambiguous regulatory policies. In this context this paper studies relationship between regulatory policies and their impact on innovation and technology capability development by exploring what role absence of regulation played in hampering or facilitating

development of inclusive innovations in the Indian medical device industry. In developing study literature development of technological capabilities in high-tech industry such as medical devices has remain a neglected area of research. This research aims to fill that gap.

Similar to pharmaceuticals and vaccines, medical devices are essential for patient care in operating theatres, at the bedside, and even before a patient is admitted into hospital, or after being discharged. The regulation of medical technologies is one of the most neglected areas in the health policy research. According to the World Health Organization “medical devices” includes everything from highly sophisticated computerized medical equipment down to simple wooden tongue depressors. In many countries medical devices regulation is still evolving phenomenon as product development is associated technological complexities and uncertainties in use.

This paper addresses the issue of regulatory vacuums and their impact on capability development, highlighting some of the difficulties caused by them. Section two discusses the relationship between regulation and innovation and impact of regulation on direction of innovation and evolution of a sector. Section 3 presents background of the medical device industry while section 4 provides details of research methodology used in this research. Section five elaborates on the case studies of three Indian medical device firms and discusses key features of inclusive innovations developed by these firms. Section six presents the evidence generated by problems associated with the regulatory situation in India as it relates to medical device development. This paper conclude that, rather than lamenting the existence of regulation policy makers should strive to create ‘smart and appropriate regulation’ which optimises opportunities to innovate and thereby benefit from scientific pursuits, new technologies and inclusive development. In short, innovation needs to be in our approach towards regulation.

2. REGULATION AND INNOVATION

Healthcare sectors are perceived as a research focused and supply driven to a much greater degree than other manufacturing sectors. However, the extent to which the sector is influenced by factors other than science and technology is often underestimated (Chataway et al, 2010). Regulation and industrial policy forms an important third pillar to two other strands of (science and technology) of healthcare and biotechnological industries. Government aims to stimulate and control innovation through variety of routes; some of them are direct such as industrial policy, tax concessions and some other are indirect such as infrastructure creations and regulatory policies. For example, the impact of government support and regulation can be observed in case of evolution of European and US pharmaceutical industry. In 1880 German and Swiss industries were at forefront at development and manufacturing of drugs. However with outbreak of World War II US government organised a massive research and production effort that focused on the commercial production techniques and chemical structure analysis (Henderson et al., 2007). This system significantly improved productivity and led the foundations for the industry that helped US industry to leapfrog European pharmaceutical companies. In healthcare and biotechnological sector regulation can have similar impact and regulatory policy is one of the key instruments of government intervention.

2.1 Influences of regulation

The primary objective for regulation is to ensure safety and efficacy of products for mass consumption. Most healthcare and biotechnological products require regulatory approval before entering the market. The granting of market approval turns on the provision of data that satisfied the regulator that the product is a quality product that is safe and effective, and that there are risk management plans in place. This role is paralleled by the European Medicines Agency (EMA), whose mission is to foster scientific excellence in the evaluation and supervision of medicines for the benefit of public and animal health. Obviously, such regulatory frameworks have significant implications for the market-entry of products, including the cost and timing of market entry, all of which affects the sustainability of a firm's market position (Henderson et al., 1998).

Second key objective of regulation for government is to create a set of incentives and constraints to influence behaviour of economic agents with the assumption that these rules will protect public health, stimulate development of effective products and ensure quality of those products. Government aims to remove information asymmetries and design clear rules for all stakeholders with the use of regulatory control (Chitniz, 2002). For example, Cockburn (2004) credits Bayh-Dole Act in 1980 for setting clear rules for universities, small business and non-profit organisations to earn on intellectual property rights of their inventions. This regulation gave US universities, small businesses and non-profit organisations the right to retain intellectual property rights to inventions deriving from federally funded research. It allowed individual scientists to launch new biotechnology focused firms, which acted as a "middlemen" in the transfer of technology from Universities and established firms. These start-ups developed new "architectural competencies that enabled them to act as integrators across research, manufacturing and process development and thus played a critical institutional role in emergence of biotechnology sector. This regulation allowed emergence of this new institutional innovation that formed foundation for rapid emergence of the biotechnology industry in US.

In some cases regulations has made significant changes to growth of healthcare sectors. For example, the ruling in a landmark case of the 1980s, *Diamond vs Chakarvarty* and Patent and Trademark Amendments of 1980s has been credited with the rise of the biotechnology industry. *Diamond vs Chakarvarty* case involved a patent claim on a genetically modified, oil eating bacterium. USPTO rejected the claim on the basis subject matter was living organism and ineligible for patent protection. In 1981 the US Supreme Court granted extension of patentability to genetically engineered bacteria and by that establishing the right for very broad claims (Merges and Nelson, 1994). It created tight appropriability regimes and well define rules that led to foundations to emergence of biotechnology sector. It is often stressed that the lack of adequate patent protection was a major obstacle to the development of the biotechnology industry in Europe.

Third important objective of regulation is to create sustainable institutional modes that have enough flexibility to accommodate evolution particular set of economic activity For example; in 1990 the dynamics of the US healthcare market was transformed due to introduction of the Hatch-Waxman Act. This act was proposed to incentivise development and production of cheap generic drugs for poor populations of the country while ensuring benefits for pharmaceutical firms on their innovative product

development. It allowed entry of generics medicines by eliminating the clinical testing aspect. Firms could file for generic market entry on the basis of bioequivalence studies and that significantly reduce entry barriers for firms operating in generics area. Moreover, the first firm to file an application for making a generic equivalent to a branded drug receives a 180-day period of exclusivity, while manufacturers of branded drugs are allowed to request a 30-month postponement of the FDA's approval of generic drugs that arrive before their patents expire. This regulatory change gave rise to affordable generic market, had impact on business models of pharmaceutical firms and opened a new market to the leading Indian firms (Kale and Wield, 2008). In 1980, generics held only 2% of the US market (Henderson et al., 1998).

One example of the way in which policy and regulation have impacted on the evolution of the sector in developing countries is provided by rise of Indian pharmaceutical industry as a main source of cheap generic medicines all over the world. The Indian government intervened through regulatory policies and created an industry with required credentials to better serve the needs of its people (Kale and Little, 2007). Shifts in policy and investment encouraged the growth of an industry and generated inclusive innovations that helped in satisfying the healthcare needs of poor people with producing medicines at an affordable prices being the main concern.

2.2 Perils of regulation: “Overregulation” and “overdosed”

Majority of healthcare and biotechnological products needs regulatory approvals to enter markets and that has significant implications on the entry of the product, its cost and on firms' ability to sustain market position once product is approved (Henderson et al.,1998). As a result regulation strengthens the government's authority over all stakeholder and their activities in healthcare and biotechnological vale chain. This strong influence of regulation and government control has become a contentious area in studies of regulation and innovation. Boundaries of regulation and limits to governance have emerged as key areas of focus (Lyal et al.,2009). Regulation is criticised for introducing a set of unintended constraints that increases cost and hampers direction of innovation (PWC, 2002). Espein (2006) has termed this phenomenon as 'overdose' of regulation while Havighurst and Richman (2006) calls is 'overregulation'.

First key criticism against regulation is that increases cost of innovation. Regulation has a significant unintended impact that reaches far beyond simply determining the kinds of products that are developed. It creates more unintentional subtle incidental barriers. For example, Cockburn (2004) criticises introduction of Bayh-Dole Act of 1980 for rising cost of pharmaceutical R&D. Till introduction of this act there was much of movement of ideas, candidate molecules, research materials and researchers back and forth across the for profit and non for profit divide. However, introduction of 1980 Act led to emergence of biotechnology companies, many of which positioned themselves as an intermediately sector between academic research institution and Big pharmaceutical firms. Academic scientists played a particularly important role in the founding of these intermediately companies. Cockburn (2004) argues that some of the increase in R&D spending represents payments for access to upstream science of the kind that used to be obtained 'for free' by pharmaceutical firms but now firms has to pay price in the form of license agreements with biotech firms and universities. Curtis and

Schulman (2006) argues that regulation may profoundly affect cost by stifling innovations in service delivery and quality improvements by demanding lot of documentation and paperwork.

Second key criticism against innovation is that it stifles creativity by creating barriers to 'out of box' thinking. Supporting this argument Curtis and Schulman (2006) point out that the presence of regulation may effectively prevent disruptive technological improvements from occurring. Based on Christensen (2007) theory of disruptive innovation, they suggest that in weakly regulated market, a disruptive innovation may emerge because of the low threshold of mandated requirements exist and that allows introduction of products with basic features. In highly regulated markets this is not possible as products are expected to be of 'ideal standards' and these standards exceed the performance requirements of the average consumer. In such cases requirements established by regulations might be ideal and not optimum and thus exceeds the requirement of basic product application, preventing disruptive innovation. For example in weakly regulated Indian automobile sector Tata Motors could innovate with material and interiors while designing indigenous car and thus could launch world's cheapest car with basic safety features. Tait et al., (2007) provides examples of information technology sector. They compare the lightly regulated information and communication technology (ICT) sector with the heavily regulated life sciences. In last two decade IT sector has much shown greater degree and rapidity of change in products and capabilities arising from technological innovation. It is quite evident that these small innovations have basically emerged from small start-up companies. In short period of time these small star-ups are able to build up resources and has upstaged existing industry players to emerge as a major players on the basis of innovations that effectively challenge the status quo. However in a strongly regulated market the performance threshold is higher; all products must meet mandated requirements to enter the market. IT sector has witness emergence of new dynamic players taking sector forward with their innovations while in contrast life sciences sector, has suffered domination by a relatively small group of multinational companies. In healthcare sector regulation now forms an insurmountable barrier to entry for any start-up company with an innovative idea that might challenge the status quo. Thus under current circumstances, regulation prevents development of the radically innovative technologies that could provide the opportunities to move the sector onto a new higher value-added innovation trajectory (Tait et al., 2007).

Third key criticism against regulation is that it stagnate growth of the sector by creating rigid entry barriers. For example, the 1962 Act demanding proof of efficacy approval requirement has introduced high cost and long delays in pharmaceutical R&D process. As a result resources and capabilities required in taking a new product through the regulatory system ensure only MNC firms owners of those resources and capabilities to operate and dominate innovation cycle. Small companies totally rely on MNC firms to take their products through complete innovation cycle to markets or become acquisition targets, in both cases tailoring their innovation strategies to MNC firms. Tait et al., (2007) points out that regulation also determines overall company strategies, types of company that can succeed and the structure and dynamism of the sector as a whole and as a result overall structure of the pharmaceutical sector has remain unchanged for the last fifty years, despite numerous potentially path-breaking scientific discoveries. For example, Grabowski and Veron (1983)

argues that as a result Kefauver-Harris Amendment in 1962 the US FDA role has shifted from as essentially an evaluator of evidence and research findings at the end of R&D process to an active participant in the process itself. The 1962 amendment introduced proof of efficacy requirement for approval of new drugs and established regulatory controls over the clinical testing of new drug candidates.

This literature review suggests that a regulation can create artificial barriers in promoting disruptive innovations, affect evolution of sectors and reduce possibilities of the affordable healthcare and biotechnology products. Without disputing this observation this research aims to study what happens to growth and development of healthcare sectors in absence of any regulation. This review points out that regulation and innovation studies haven't paid enough attention to issue of absence of regulation and its impact on development of healthcare sectors. This research tries to fill that gap.

3. BACKGROUND: THE MEDICAL DEVICE SECTOR

Medical devices sector includes 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. 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 device means any instrument, implant, machine, intended to be used, alone or in combination, for human beings for one or more specific purposes such as diagnosis, prevention, monitoring, treatment or alleviation of disease (Shah and Goyal, 2008).

In medical devices sector patents have much less importance in many segments of the device industry. Unlike pharmaceutical industry in the medical device industry, the basic principle can be patentable, but specific devices usually are not. Thus it is possible to design a medical device for a specific application in a number of different ways. The innovation often lies in the underlying principle being used in the particular application. For example, the concept of transducer was patentable, although specific implementations of the idea were simply design exercises and did not provide patentable material. In instrumentation products, patenting the design of the instrument itself is a futile exercise because it is not difficult to design another instrument in a different way that performs in exactly the same manner. In comparison to drugs, the device innovation process is characterised by a much higher degree of incremental change, which continues to occur throughout the various stages of pre-market testing. Surgical procedures that do not involve new products and new clinical practices tend to undergo a less formal evaluative process. They do not require pre-marketing regulatory approval, but in the case of major innovations payers tend to act as the gatekeepers requiring evidence prior to reimbursement and more generalized diffusion (Foote, 1991).

The global medical device market is currently valued at USD 210 billion in 2008 and has grown at a CAGR of 6% post 2000 (WHO, 2010). The USA is largest consumer of medical devices and leads the world in the production of medical devices. According to global statistics, 85% medical devices are manufactured in the USA, in Japan and in European Union countries while the same regions also account as major market for medical device. The USA has a medical device market valued at more than \$100 billion in 2008, roughly 41% of the world's total. It is followed by Japan

(10%), Germany (8%) and France (4%).

TABLE 1 HIGHLIGHT OF MEDICAL DEVICES FOR THE USA, EU AND JAPAN (Altenstetter, 2010, WHO, 2010)

Medical devices	USA	EU	Japan
Production			
Global Share	51%	30%	10%
Value (2005)	\$92.0 billion	\$38.0 billion	\$14.2 billion (2004)
Consumption			
Global share	50%	30%	10%
Value (2005)	\$90.2bn	\$38.1bn	\$19.0 (2004)

Based on strong economic growth and large population China and India is increasingly emerging as an important medical device market. China's overall market for medical devices is estimated to reach \$5 billion in 2010 while Indian market is valued at \$3 billion. China and India are focusing on developing its medical device regulatory regimes and domestic market devices sector. The private healthcare sector in India is expanding significantly to meet the needs of India's growing middle class, population of 300 million with disposable income and increasing medical expectations

3.1 Status of medical device regulation

The medical device industry (MDI) is a semi regulated sector globally and regulatory environments have significant implications for industry's performance. Foote (1991) argues that public policies such as government regulation, product liability statutes, reimbursement rules, and government funding for basic research have had a significant impact on the production and diffusion of new medical devices. Medical devices around the world are classified based on their safety requirements and standards of quality to be set and several criteria are considered to evaluate the potential risk: degree of invasiveness, duration of contact, affected body system and local versus systemic effects. The regulation of medical devices is a vast and rapidly evolving field that is often complicated by legal technicalities. The early models for medical device regulation were based on drug regulation however due to inherent differences in drugs and devices uncritical application of drug model lead to serious difficulties. This led to evolution of a legally autonomous medical device regulatory framework. US took lead in development of medical device regulation in 1976 while European Union started framing their regulations in 1990.

In the 1976 the US congress enacted the 'medical device amendments' which gave FDA authority to regulate medical devices. In 1990 US government pass the new law 'The Safe Medical Devices Act' that introduced pre-market notification as the primary safety and effectiveness in conjunction with a post-market strategy. The post market regulation strategy included: mandatory reporting of adverse events or problems, device tracking systems, performance standards for class III devices and recall authority for FDA and imposition of civil penalties on manufacturer. In the US, the devices fall into

three categories – I, II or III, with class III devices with the highest risks and hence requiring the most stringent controls. In the US, medical devices can reach the market through two regulatory processes: the 'pre-market approval' (PMA) process or the '510(K)' process. The most rigorous is the PMA process, which requires scientific evidence of safety and effectiveness for a device's intended use obtained through ethically sound clinical trials. Class III devices, which support or sustain human life and include many novel cardiac devices, are subject to the PMA process. In contrast, a device that goes through the 510(K) process need only have evidence to demonstrate that it is substantially equivalent to, or at least as safe and effective as, another device that has already been cleared by the FDA (ie: the new or investigational device must be shown to be as safe and effective as a predicate device). The 510(K)'s route and evidentiary demands for 'substantial equivalence' makes it much quicker and cheaper for device makers than the PMA process, and the 510(K) process enables evolutionary changes to roll out more quickly, and it is such changes that are the hallmark of many device niches, including orthopaedic implants.

In 1990 European Union issued directives under the 'New Approach' that harmonise different regulatory requirements for medical devices in different European countries and protect public health from unsafe medical devices. The 'New Approach' involved specifying only the general essential requirements those were general and mandatory. These essential requirements are divided into two types: General requirements applicable to all medical devices and the more specific requirements for 'design and construction' that may or may not apply to a particular device. Medical devices that comply with New Approach directive carry the CE mark of conformity and can be marketed throughout the European Economic Area (EEA). In the EU, devices are categorised in a four-class scheme; I, IIa, IIb and III.

Class I involves products such as hospital beds, wheelchairs, spectacles, gloves, Stethoscopes, etc., Class II cover syringes for infusion pumps, devices intended to channel blood, contact lenses, hearing aids etc.,

Class IIb includes haemodialysers, Urethral stents, insulin pens, prosthetic joint replacements, surgical lasers, blood bags, contact lens solutions, incubators etc.,

Class III devices cover absorbable sutures, cardiovascular & neurological catheters, heart valves, spinal stents, contraceptive devices, antibiotic bone cements, heparin-coated catheters etc. However these classes and devices are not rigidly categorised. For example in 2004 key products in the implant sector were reclassified from IIb to III, the highest risk category.

Rather than a public authority, certification bodies implement and monitor compliance with New Approach directives, with varying involvement of a competent authority depending on the risk category of medical device. The conformity assessment procedures allow manufacturers to demonstrate devices satisfy essential requirements. Class I device manufacturer need to consider only one procedure while higher risk device developers can choose from one of the several conformity assessment procedures. These choices range from product testing to establishing a full quality assurance system that includes design control and risk analysis for Class III devices.

In Japan, Ministry of Health, Labour and Welfare (MHLW) is a strong central ministry combining political authority and responsibility for the entire medical device regulatory framework, the national

health protection systems, public health as well as medical facilities. Medical device regulatory framework revised in 2005 combines both EU and FDA practices. Class I can be put on the market without any intermediary while Class II require a third party certification. Class III and Class IV devices need government approval which comes in two steps. The PMDA, a regulatory agency created in 2004 reviews and recommends decision to the MHLW but has no authority to make final decisions. Altenstetter (2010) points out that unlike Europeans and Americans, the Japanese have not fully benefited or contributed to advances in the medical devices due to highly bureaucratic, lengthy and delayed approvals of new medical devices. It clearly suggests the key role of regulations in creating an environment that support innovative product development.

3.2 The Indian medical device industry

The medical technology market in India was estimated at US\$2.75 billion in 2008 (NIPER, 2010). The Indian medical technology industry is highly competitive and fragmented, with domestic firms primarily manufacturing low technology products such as disposables/ medical supplies, and MNCs dominates high-end medical devices market. There are about 14000 medical devices marketed in India and more than 70% of devices are imported from advanced countries such as US, Japan, UK and Germany. MNCs from the USA are leading suppliers of devices with more than 28% products valued \$400 mn coming to the India in 2008. There are almost 700 local manufacturers but most make low value products such as needles and catheters, leaving high-tech specialists devices such as transducer and heart-valve to MNCs such as St. Jude, GE, Siemens. Kamath (2010) explains the state of the Indian medical device industry that,

“The words India and medical technology are seldom used in the same sentence. An indigenous medical device industry has been virtually non-existent. Local players, with some exceptions, have struggled to shed the ‘low-tech, low quality’ tag. For instance doctors faulted local pacemakers for being too bulky and difficult to implant with leads (that connect the pacemaker to the heart muscle) fracturing easily”.

Most MNCs are involved in distribution of medical technology products, though some of them have set up manufacturing operations in India. MNCs seeking to enter the industry typically form joint ventures with local manufacturers, establish subsidiaries or employ local agents to distribute their products. However, increasingly these companies are moving away from the practice of importing through local agents and setting up subsidiaries. According to Deloitte (2010) report key categories of items that are imported into India include imaging equipment, pacemakers, orthopaedic and prosthetic appliances, breathing and respiration apparatus, and dental equipment.

This report further points out that even though India’s medical technology industry is primarily import dependent, at the same time, nearly 60% of what’s being manufactured is being exported. However, similar to domestic market Indian firms dominate low-tech equipment and the exports of high quality, high tech Indian products are negligible compared to other developing countries. Prof. Valiathan, the father of the Indian medical device industry explains:

“The Indian industry makes some low technology items which they are exporting. They don’t have any incentive to invest in hi-tech items”

(Telegraph, 2013)

It is quite clear that similar to pharmaceutical and biotechnology products the medical device industry in India needs to create innovations appropriate to meet the healthcare needs of all income segments. In a resource constraint country such as India, domestic firms have to engineer devices that can be affordable, reliable, resilient, easy to distribute, and easy to use. Thus solutions have to be found by reducing costs, improving durability and focusing on serving basic healthcare needs. Prof. Valiathan highlights the social cost of import dependence:

“Ten per cent of the imported items is accessed by only 10 per cent of our population. For the MNCs, it is a huge market, Rs 120 million. But we have a 1.2 billion population, if we want to give them access to such items, we need to develop them ourselves”

(The Telegraph, 2013)

This is where regulatory policies play a significant role due to their influence in facilitating or hindering development of appropriate medical devices. Despite this high percentage of imports and consumption till 2005 India did not at all regulate any of the medical devices (both local and foreign). In case of India absence of clear regulations, multiple levels of government authority involved in enforcing the guidelines, as well as inconsistent interpretation and application of the regulatory guidelines by customs officials at the ports, state drug controllers, and officials within CDSCO created a prolonged and cumbersome regulatory pathway, especially for new products (Deloitte, 2010). In this context this research investigates key factors that hamper the development of inclusive innovations the Indian medical device industry.

4. RESEARCH METHODOLOGY

This research explores the role of regulation and investigates its impact on the innovation and technological capability development in this important high-tech industry. Data collection involved conducting preliminary research to identify innovative Indian medical device firms and indigenously developed products. Following preliminary research, semi-structured interviews were conducted with key personnel from each company as well as key stakeholders associated with the industry. Participants were chosen from the medical, scientific, academic, policy, legislative and regulatory communities. Specifically interviews were conducted with a leading cardiac surgeon, a biomedical engineer, a local entrepreneur, a healthcare sector journalist, president of pharmaceutical industry association and a government official working with drug controller of India.

Based on this preliminary data collection three companies; Shushrut-Adler, Medived, Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST) were used as case studies. The firms were involved in developing products such as heart valves, orthopaedic implants, and blood bags.

Table 2: Firms under study (company website, author communication with company, Deloitte, 2010)

No	Name of the firm	Year of starting	Medical device	Impact
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1	Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST) + TTK Healthcare	1974	Heart Valve	Cost is 50% less below the comparable heart valve produced by MNCs
2	Shushrut-Adler	1973	UMEX system	Absence of comparable products from MNCs in the Indian market
3	Medived	2007	Pacemaker	Cost is Rs. 20,000 to 25,000 below the comparable pacemakers produced by MNCs

In each firm interviews were conducted with the Head of R&D and the CEO or Managing Director of the firm. Questions focused on the current status of the medical device industry, its regulatory framework and government initiatives to promote medical device research and manufacturing, and how it compares with India's pharmaceutical/biotech industry. Open-ended questions and a relatively unstructured interview schedule were used to encourage participants to speak in their own words about their experiences, observations, opinions, and desires.

Data analysis was carried out using a theoretical framework based on innovation systems literature. Pattern matching technique was used for data analysis and data was categorised into following three themes;

Theme 1 – Industrial Policy and government initiatives, Institutional support in form universities and research institutes public sector firms,

Theme 2 - Entrepreneurship and role of Indian and MNC firms

Theme 3 – Regulatory framework and its role.

5. Firms under study

This section presents case studies of three firms and one innovation each of these firms developed. Sree Chitra Tirunal Institute is a research hospital but have an extended product development wing.

5.1 Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST) +TTK healthcare

In 1973 Prof. Valiathan started Sree Chitra Institute with help of Royal Family of Travancore and in 1976 initiated a project to develop indigenous heart valve in India. Most of the Indian hospitals import heart valves developed by MNC medical device companies such as Johnson & Johnson Services Inc. and Boston Scientific. In 1980 the institute was taken over by the central Indian government and Department of Science and Technology started providing funds for heart valve project. It was decided that the indigenous valve would be a mechanical device, not one that used human or animal tissue. However development of heart valve proved a very challenging process. The artificial valve must withstand the stress of opening and closing some 40 million times a year while the materials used for

the valve have to be compatible with blood and human tissues (Gopalraj, 2009). This project suffered a major setback when a model failed to work in sheep due to faulty material and the search for new material to replace it had to start anew. Finally, in December 1990, after clearance was obtained from the Institute's ethics committee, the first Chitra valve was implanted in a patient. Prof. Valiathan explains the process:

"Chitra Valve development happened in the late 70s. In a small institute in Trivandrum with limited resources, we could demonstrate that it could be done. By resources, I don't mean just money but technology resources, like different types of materials, textiles, fine fabrication techniques; all these were available in India. Only thing is you had to shop around, and find them, integrate them and then only you could make a device. We showed that this was feasible.

(The Telegraph, 2013)

In late 1991, TTK Healthcare, one of the constituents of the TTK group, took the technology for the manufacture of the valve. Raghu (2007) points out that the Chitra-TTK mechanical valves are sold at about a quarter cheaper than similar imported valves. But absence of specific regulation for the industry, and coverage under the Drugs and Cosmetics Act has created . Dr. Valiathan explains, "At the time, Sri Chitra was on the cusp of developing a range of local alternatives to imported devices, but we had no clue whose approval to take to launch product. Until there's a law all decisions become ad-hock" (Kamath, 2007)

5.2 Shushrut- Adler Surgicals

The Shushrut Surgicals was established in 1973 by a first generation entrepreneur and started its operation by selling fracture management implants and instrumentations. In 1992 Shushrut embarked on development and manufacturing by setting of Adler Mediequip Pvt. Ltd. the eventual manufacturing company of the group. The current managing director of the Shushrut-Adler Group, Ajay Pitre is a chairman of the medical device wing of the industry association body. He is also a member of the core committee advising the government on the formation and implementation of the Medical Devices Regulation standards in India.

In post 1992 Shushrut developed collaboration with orthopaedic surgeons, academic institutes with in-house engineering teams. One of these collaborations led to the creation of the first truly indigenous invention in the field of orthopaedics, the Universal Mini External Fixator system. Conceived by a group of eminent orthopaedic surgeons in Mumbai, led by Prof. B.B Joshi and Prof. Laud, the UMEX system enables clinical solutions in areas not addressed by products and devices from the Western world. UMEX enables effective treatment and rehabilitation in the case of extremity fractures (fractures in the hands and feet), crushing injuries of the extremities and paediatric deformities like club feet and club hand. The superior clinical outcomes possible with UMEX have led to adoption of the system by some prestigious centres in the U.K, Germany and U.S. However according managing director of the company lack of regulation in early years created hurdles in bringing innovative product to the market while in later years categorising devices under Drugs and Cosmetic Acts led increased cost of development by demanding inappropriate infrastructural changes.

5.3 MediVed

Medived was started by local entrepreneur Dinesh Puri in 2007 with aim of developing medical devices appropriate and affordable for local populations. He explains the motivation:

“I found that 90 % of the medical devices industry is controlled by the western world–US and Western Europe. It was even more interesting that 90 % of their revenues came from the western world. So I thought that how can you have people who live outside the western world consuming less than 10 % of these devices. In the case of pacemakers, the penetration level in the US is about a 1,000 per million population, and Western Europe has 1,300 per million. In India’s case of it is just 15 per million. In China it is 50 per million. This was the motivation to get into the field of medical devices”

(DARE, 2010)

Realising the challenges in developing pacemaker from scratch Medived decided to go with collaboration route and brought in pacemaker technology from a South American company, CCC who had tried and tested technology and were supplying markets around the world for 35 years. After acquiring technology from CCC Medived embark on developing further innovations to reduce cost of production and refine technology to suit local needs without compromising quality. Similar to other medical devices pacemakers involves integration of multiple scientific disciplines and has to last for at least 10-15 years. Medived hired an engineer from Indian Satellite research organisation who used to make PCBs for satellites to work on engineering aspects of pacemaker manufacturing. In 2009 Medived set up a vertically integrated manufacturing facility where everything associated with pacemakers would be manufactured. Dinesh Puri further explains the significance of indigenous pacemaker development for meeting healthcare needs of local population:

“ In the US, these devices sell for \$4,000-8,000. In India, we sell them between \$1,000-2,000. It is a fact that many of these western companies also sell at lower prices than in the US. Our focus is to make the devices more relevant for our markets. In the US, everything is paid for by insurance. So people replace the devices every four to five years. In India, we are not used to that; we want the device to last for much longer time. In most emerging markets, 80percent of our healthcare is paid for by the patient. In our markets, we will have to find our own solutions”

(DARE, 2010)

Similar to Sree Chitra institute’s heart valve Medived’s indigenously manufactured pacemaker faced obstacles in gaining market acceptance due to doctor’s doubts about quality of the indigenously developed medical devices. This issue certainly has direct links with absence of regulation to govern the Indian medical device industry as well as lack of trust in the Indian government’s regulatory set up.

6 ANALYSIS AND DISCUSSION

There are three key salient issues that describe the current status of the Indian medical device industry and they relate to flawed industrial policy, lack of entrepreneurship and government regulation. This paper focuses on the lack of regulation and its impact. Our analysis clearly show that lack of regulation had more serious impact on availability and access of appropriate medical devices to the poor population of India

6.1 Era of no regulation (1947-2005)

In case of India till 2005 there was effectively no quality regulation for medical devices that were either imported or manufactured in the country. Dr Valiathan comments on neglect of the industry,

“Devices suffered from neglect by the medical profession, technologists, industry and Government”

Kamath (2007) suggests that in the early 1980s the government did realise the need for medical device regulation however problem was clear lack of understanding in how medical device works, its mechanism of action and criteria of performance measurement. Harper (2003) alleges that in some categories imports of used material was allowed into India and as a result low quality devices were used in the country. There was no regulatory control on how device actually works its technical specifications and performance. There was little information available on medical devices apart from that provided by companies for marketing purposes. All medical devices were sold in India without any monitoring by regulatory authority or reporting by hospitals. For instance, in case of Boston Scientific and Johnson and Johnson withdrawal of its stents worldwide in 2004, there was no independent information available in India on how many of these devices may have been used or if any patient had reported any adverse event (Harper, 2003).

6.1a Handicapped local manufacturers

There are not set uniform standards for these products and as a result quality and performance are not tested. This lack of regulation created a significant hurdle for local manufacturer to develop products and enter the market domestic as well as international markets. These local manufacturers had no idea whose approval to take to launch product and all regulatory decisions were ad-hock. Local manufacturer struggled to sell their products competitively in the market without proper authorisation and often fare poorly against MNC products which are approved by stringent western regulators and backed by huge amounts of clinical trials data. Murthy (2004) points out that from 1994 till 2004 there were more than 11000 valve procedures were done per year in India, only 1000 valves developed Sri Chitra Research Institute (a leading Indian research institute) were used even though it costs less than 50% of the average of all the imported valves. The Indian clinical community is averse to using devices of the Indian manufacture because of uncertain standards and lack of quality assurance. Thus absence of regulation and any direction from government severely handicapped local manufacturers in the market place.

6.1b MNC's Monopoly Rent

MNC charged high prices with significant profit margins for their devices as the Indian clinical community is averse to using devices of the Indian manufacture because of uncertain standards and lack of quality assurance. MNC sold their products in the Indian market without really taking into

consideration of production cost as there were no local competitor to compete for low prices and no regulation to monitor their profit margins. There was no transparency in the production cost and selling prices varied widely in the market. Most of imported medical devices such as cancer diagnostic, medical imaging, ultrasonic scanning, plastic surgery equipment and polymerase chain reaction (PCR) technologies specifically at high-tech end were sold with high gross margins. Indian companies often fare poorly against premium global brands which are approved by stringent western regulators and backed by huge amounts of clinical trials data. Thus total lack of regulation created skewed market in favour of MNCs and as a result these companies could charge 'monopoly rent'. A leading cardiac surgeon comments on domination of MNCs firm on the Indian medical device industry,

"We are compelled to import 90 per cent of high-end instruments, devices, etc for our hospitals at high cost and replace them every 3-5 years at still higher cost. This pushes up the cost of specialised care in cardiology, neurology, etc and makes them inaccessible to the majority of Indians. MNCs estimate their Indian market as 200 million who can pay --- they conveniently ignore the one billion who can't do it"

This creates immense problem for securing access of these devices to much needed poor population of India as well as other developing countries. A leading bioengineer argues,

"the lack of regulations, paucity of raw materials and unrestricted import of finished products all conspired to daunt an intending manufacture of biomedical devices"

6.1c Mushrooming of counterfeit products

Without any regulation market was populated by spurious operators and counterfeit traders who used scrap material as raw material or import goods of uneven quality from Chinese manufacturers. Many small trading companies are mushrooming in the country which imports products from China, Korea and Taiwan at a very low rate, even lower than Indian firms' production cost. A leading bioengineer involved in development of indigenous heart valve comments,

"at the same time the market for the lower end disposables is vitiated by the unbridled manufacture of devices without any concern for GMP"

The market is flooded with non-standard look-like counterfeit products, which are sold at very low prices. A CEO of orthopaedic implants company points out the impact of these spurious traders and counterfeit manufactures,

"I still lose more business to unregistered products than to MNCs"

Many of medical devices are implanted into the human body for critical care. Implanting a poor

quality or defective device can cost the life of the patient and therefore require minimum standards and some control on prices. This lack of monitoring in India could have serious consequences for poor patients' healthcare as these people were recipients of cheap counterfeit and unsafe medical devices. In 2004 these consequences became apparent when state run JJ hospital in Mumbai used unapproved drug eluting stents on as many as 60 high risk cardiac patients. The stents were manufactured by Occam, a Netherlands-based company and marketed under the brand name Axxion. These stents were not approved for use even in Netherlands but they were marketed in unregulated Indian medical device market by the Mumbai-based trading company. Government shut down the importer and a local stent company as a result of this and both of them went to court showcasing absence of rules. As a result high court ordered government to set rules and standards for medical device industry.

6.2 Era of wrong regulation (2005 – till now)

In 2005 taking cognisance of JJ Hospital case and court order the Indian government listed 10 such medical devices under the Drugs and Cosmetics (D&C) Act, 1940. These products including cardiac stents, drug eluting stents, catheters, intra ocular lenses, IV cannulae, bone cements, heart valves, scalp vein sets, orthopaedic implants, and internal prosthetic replacements. These devices were mandated to get licenses for their manufacture, sale and distribution. These rules have been approved by the Ministry of Health and Family welfare and the guidelines issued came into force from March 1, 2006.

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 indigenous or imported. The legislation is enforced by the office of the Drugs Controller General of India (DCGI). DCGI is authorised to handle product approval standards, permit clinical trials for introduction of new drugs, and regulate import license for new drugs. However there was serious problem with medical devices under Drugs and Cosmetics (D&C) Act. In Europe and US separate laws that govern medical devices and implants while pre-independence D&C Act is meant for drugs and cosmetic only. This was followed by a widespread debate on the legal status of medical devices. Several experts excluded medical devices from the drug list as the Drugs & Cosmetics Act does not cover medical devices. It was clearly evident that the regulatory framework and infrastructure designed to govern pharmaceutical and cosmetic products is totally inadequate for governing medical devices due to the nature of difference in products, their action in human body and packaging. By mid-2008, however, industry again began to experience inconsistent application of the current guidelines causing renewed confusion and delays. These problems were sourced in part to multiple levels of government authority involved in enforcing the guidelines, as well as inconsistent interpretation and application of the regulatory guidelines by customs officials at the ports, state drug controllers, and officials within CDSCO (*Central Drugs Standard Control Organization*). Some companies struggled to get licenses for products for more than 6-7 months even if they were in market for more than two decades and had received regulatory approval for their products from European regulators (Kamath, 2007). It was clearly evident that the regulatory framework and infrastructure

designed to govern pharmaceutical products is totally inadequate for governing medical devices due to the nature of difference in products, their action in human body and packaging. For example, concept sterility differs in pharmaceutical products and medical devices. A drug has to be manufacture in 'clean room conditions' requiring certain kind flooring, air-flow and energy requirement to minimize impurities. However in case of medical devices can be sterilised at the point of use and doesn't require same production conditions such as pharmaceutical products. For instance orthopaedic surgeon orders different sizes of implants from the company and at the time of surgery sterilises only those which fits patients. A leading manufacturer of diagnostic devices explains the key issue,

"This industry is considered to be a pharma segment but really does not belong there. The authorities themselves are not knowledgeable about diagnostics industry. A device cannot be regulated as a drug"

By 2011 it became apparent that the D&C Act is not ideal for devices and rather than helping local authentic manufacturers, it endangers their survival. Globally, medical devices are regulated and the approvals acceptable in the world market are from the FDA in the US or the European CE certification. However, a similar regulatory body for Medical Devices is needed and not yet properly established in India. There is a clear lack of communication between various government departments, limited understanding of the issue on hand and severe infrastructural problems to implement any regulation. Dr. Valiathan points out difficulties in developing optimal regulation,

"The Indian Medical Regulatory Authority (IMDRA) proposed by a Government Committee would have been optimal. Thanks to turf war in the Government, it has been substituted by a Committee under the Drug Controller General of India. It is too highly centralised and too bureaucratic to promote R&D and industrial activity in relation to medical devices and instrumentation. Neither has become an Act yet"

The Indian government is still working toward establishing a medical regulatory regime but struggling to set up governance structure that can distinguish between medical devices and pharmaceuticals.

To conclude evidence presented here suggest that the Indian medical device was totally ungoverned from 1947 till 2005 and this was the period where local industry witnessed no growth, and domestic market was swamped by unaffordable devices by MNC and counterfeit products from spurious local traders. The authentic Indian device developers and manufacturers suffered the most as they struggle to again acceptability of their products due to lack of any regulation and regulating authority. MNCs enjoyed most benefit of the situation through monopoly rents severely restricting access of affordable healthcare to poor populations of India.

7. CONCLUSIONS

This study focused on exploring linkage between regulation, inclusive innovation and sustainable development by focusing on the Indian medical device industry. The case studies presented in this research highlighted significant role of regulation in the development of appropriate inclusive innovations. It clearly indicates that in case of India an appropriate infrastructure do exists but clear absence of appropriate policies. This research highlighting role of regulatory policies in facilitating innovations reveals that without effective regulation, local authentic producers compete with counterfeit operators who use scrap metal as raw material, powerful MNCs and local traders who import goods of unproven quality. Local authentic producers have to compete on price with local counterfeit producers while fight with premium MNC brands in the high end of market. It is quite apparent that stringent regulations will control MNC as well as counterfeit producers and provide fair rules of game for local authentic producers.

Some of the developing countries such as Mexico, Brazil and others have set up regulatory framework based on US FDA and EU directives. These regulatory regimes contain common structural features that concerns with safety and effectiveness of the devices. Altenstetter (2010) while accepting convergence and internationalisation of medical device regulation argues that national states and national authorities have a significant role in devising regulatory framework that is suitable for local conditions.

However need is for 'smart' regulation than just framing some rules. It is also evident from Indian government's attempt to regulate medical device market post 2005; rather than ensuring safe and effective products in fair market place, new act endanger inclusive innovations of local manufacturers and stifle supply of life saving devices. The Indian evidence suggests that, while regulation can create more equitable playing fields which can be vital for harnessing inclusive innovation, not just any regulation will do. Thus it is quite evident that regulation is an important, indeed a vital component of innovation encouragement. The developing countries should create regulations that are focused on optimal safety, efficacy and quality parameters that match consumer expectations and are suitable to the local context.

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