Mind the gap: Investigating conditions and processes influencing development of ineffective regulation in the Indian medical device industry

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Abstract

Using the Indian medical device sector as a case study, this research examines evolution of regulatory frameworks by analysing the conditions and processes through which ineffective regulatory environments come about. It also tries to unpack the complex relationship between industrial capabilities in healthcare technology sector and human health and the role of regulation in bringing the two together, and, in doing so, facilitating inclusive healthcare and development in emerging economies. It explains the ways in which absence of appropriate regulation can severely inhibit technological capability development and industry growth in developing countries. Employing historical and socio-political perspectives, the research argues that gaps in policy makers’ understanding of the underlying technology in medical device sector, together with communication gaps between government–industry and among different government departments led to governance policy fragmentation, thereby significantly contributing to ineffective regulation. In short, stakeholders should ‘mind the gap’ and make concerted efforts to bridge this ‘gap’ to avoid regulation quagmire and arrested development. This paper further reveals that the expertise mobilised to reform the regulatory and governance system was disconnected from local contexts, giving rise to a healthcare sector detrimental both to local firms and consumers but beneficial to multinational firms, counterfeit manufacturers and spurious
distributors. This lack of appropriate regulation severely hampered the development of local industrial capabilities, skewed markets in favour of MNCs and ultimately, had a damaging impact on inclusive healthcare and development in India.
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1.0 Introduction

Health technology regulation plays a crucial role in national and international industrial and health policy. History is full of examples of its role in balancing industry interests and affordable healthcare. Policy makers around the world, struggle with an inherent conflict between desire to provide improved access to safe and effective healthcare and the need to curb growth of healthcare expenditures. Clear evidence highlights the significant role of industrial and technology policies in facilitating or inhibiting growth of sectors, industries, and markets (Nelson, 2002). In healthcare sectors policies acquire an even more influential role since much technology policy is concerned with devising regulatory policies that can ensure the development of safe and effective products, therapies, and services for all (Tait et al., 2007). Altenstetter (2014:363) highlighting the significance of the understanding evolution of regulation in healthcare sector argues that, ‘how and to what extent each regulatory framework has evolved over time, and what triggered these institutional changes, remain at the centre of political, social and scientific forces that together shape national regulators’ responses to new challenges’.

Unsurprisingly, the form, scope, and stringency of regulation have been, and continue to be, much discussed, with governments frequently struggling to devise appropriate regulation that balance all stakeholders’ interests. Studies of regulation in healthcare industries clearly show its impact on shaping innovation trajectories, influencing industry structure and determining firm level technology strategies (Faulkner, 2009). In developing countries regulation is strongly linked with preventing counterfeit products, and the appropriateness and enforcement capacity of local governments (Harmon and Kale, 2015). Despite the ever-expanding knowledge base, Sorenson (2012) argues that more research is needed to assess factors and processes influencing the evolution of regulatory frameworks in different contexts and their impact on local manufacturers and health systems. This paper explores the evolution of regulatory framework and its impact on technological capability development in healthcare sector in the developing country by focusing on the Indian medical device regulation.

Similar to pharmaceuticals and vaccines, medical devices are essential for patient care in operating theatres, at the bedside, even before a patient is admitted into hospital, or after discharge. According to the WHO (2012) “medical devices” includes everything from highly sophisticated computerised medical equipment down to simple wooden tongue depressors. There has been extensive research that explored the evolution of regulation and its impact on pharmaceutical and biotechnology industries but regulation in medical device industries has remained a neglected area of research in social science and health policy studies (Altensetter and Premanand, 2010). Only a few studies have been published focusing on medical device regulation (Altensetter 2003; Altensetter 2008; Altensetter 2012; Altensetter and Permanand 2007; Kramar et al. 2012; Kramar et al. 2013). In developing countries some research has focused on the issues of diffusion and access of medical devices (WHO, 2012; Kale, 2011, Nadvi, 1999; Loureiro et al., 2008). Yet, the regulation and development of appropriate medical devices affordable to local population appears under researched and needs more attention. Using the Indian medical device industry as a case study, this research tracks evolution of Indian medical device regulation and analyses its impact on the local manufacturers and availability of affordable healthcare. This paper builds on the work of Altenstetter (2010) and Faulkner (2009) on healthcare regulation in healthcare sectors and
takes it forward by revealing how regulatory institutions evolve in a major developing country.

The Indian medical device industry provides an appropriate setting to conduct this research. Over the years the Indian medical device regulatory framework has oscillated from lack of regulation to inappropriate regulation. Further, compared to the Indian pharmaceutical and biotechnology industries, medical device industry has struggled to make significant impact on the local healthcare provisions. Some Indian medical device firms are indeed involved in the development of medical devices and case studies of these firms provides empirical basis to this study. Employing qualitative methodology this research explores how regulatory institutions evolve, what factors trigger that change and examines impact of these changes on local firms and affordable healthcare.

This paper shows that evolution of Indian medical device regulation was profoundly shaped by the limited understanding of the medical device industry among policy makers; by policy fragmentation within government departments; and an absence of linkages between industry associations and government. It further reveals that the expertise mobilised to reform the regulatory and governance system was disconnected from local contexts, giving rise to a healthcare sector detrimental both to local firms and consumers but beneficial to multinational firms, counterfeit manufacturers and spurious distributors. Indian medical device regulation oscillated from absence of regulation to ineffective regulation, with negative consequences for the local health system and industrial development. It hampered development of technological capabilities in the Indian medical device industry by increasing barriers to entry and skewing the market in favour of MNCs.

This study is the first to provide an in-depth analysis of the conditions and processes involved in evolution of medical device regulation in a developing country and its impact on the local market, firms and access. This paper is structured as follows. Section two discusses drivers and significance of regulation in healthcare sectors. It highlights the key issues that have shaped medical device regulation in advanced countries and provides a brief literature review on medical device regulation in developing countries. Section three explains our research methodology. Section four provides a periodisation of the evolution of regulation of the Indian medical device Section five six presents the conditions and processes influencing development of ineffective regulation in the Indian medical device industry. Section six concludes.

2.0 Regulation in healthcare: Evolution and impact

The healthcare sector is witnessing an increasingly expanding domain of innovative biomedical technologies, promoted as radically changing the character of medicine, healthcare and human health itself (Sorenson, 2015). These developments pose significant challenges for law, regulation and governance. The life science industries and biomedical innovation are a significant part of government agendas and a major subject of public concern about risks and benefits (Faulkner, 2012). Regulation policy has emerged as an important pillar of technology policy and an integral part of government intervention to stimulate and control innovation. Regulatory policy in healthcare sector adds a new challenge as it straddles the boundaries of several disciplines and requires theoretical, analytical and conceptual insights from other disciplines complementing insights from law and political science (Altenstetter, 2014). Perspectives from innovation systems literature suggest that innovation and regulation are path dependent processes influenced by state and non-state actors (Nelson, 2002). They further suggest that in practice, regulation of health technologies has inherent
limitations and challenges (Sorenson, 2015). Here regulation is viewed as ‘a process of involving sustained attempt to control, order or influence the behaviours of actors so as to produce identified outcomes’ (Harmon and Kale, 2012). Over the years the regulation of healthcare technologies has become more vital as well as highly contentious. The nation state is seen as a central actor in setting regulation norms. But the global nature of activity means that state-level governance must engage with international and global forms of governance, public and private, in its search for efficient modes of improving society’s access to innovation (Faulkner, 2012). All this means that environment within which decision-making is exercised is spread among actors with varying perspectives and diverse objectives. However, some objectives are common to these diverse stakeholder agendas: to ensure safety, efficacy and quality of products for mass consumption, to create a set of incentives and constraints to influence behaviour of economic agents with the assumption that these rules stimulate development of safe and effective innovative products, and to develop sustainable institutional modes that have enough flexibility to accommodate evolution particular set of technologies.

The regulatory environment in which complex and innovative healthcare technologies appear has become extremely politicised with each actor trying to exert influence to suit their objectives. These innovative technologies need regulatory approvals to enter markets and that has significant implications for the product life cycle, its cost and firm competitive advantage in market (Henderson et al., 1998). Building on this, Tait et al., (2007) and Altenstetter (2014) point out that in the healthcare industries regulation has a strong impact on market behaviour, firm strategies, dynamism of the sector and access of new technologies to patients. In a nutshell they argue that regulation influences evolution of the sector and patient’s access to advanced medical technologies. Due to its widespread influence, regulation strengthens the government’s authority over all stakeholders and their activities in healthcare technology value chain. In this context, Sorenson (2014) points out regulation inevitability brings together public and private interests in a process where there are potentially winners and losers and the perception of outcome is highly contingent on each party’s point of view. For example, regulators often face political pressures and stakeholder resistance, leading to problems with compliance or hastened approval processes that may introduce later safety risks or actualised injury (Sorenson, 2015). This strong impact of regulation and government control has become a contentious area in studies of regulation and technological innovation in healthcare sector, with boundaries of regulation and limits to governance emerging as key areas of focus (Lyall et al., 2009).

This literature review shows that the relationship between regulation and technological innovation can have significant implications for sectoral dynamics and provision of inclusive healthcare. In the resource constraint environment of developing countries, the evolution of healthcare regulation and its linkage with capabilities of local manufactures and health systems have been generally poorly understood. The evolving medical device regulation in India offers an opportunity to study conditions and processes involved in its evolution, its impact on capability development and provide some insights that are useful to other countries struggling with issues of the healthcare technology and regulation. The medical device industry (MDI) is a semi-regulated sector globally and regulatory environments have significant implications for industry’s performance. Medical devices occupy a central role in provision of affordable healthcare and to date, medical device regulation has remained a neglected area in social science and health policy studies (Altenstetter, 2014, Sorenson and Drummond, 2013). There have some studies that looked on medical device regulation in advanced regions (Basu and Hassenplug 2012; Kramer et al. 2012) and discussion on
challenges with current regulation systems (Cohen and Billingley 2011; Freemantle 2011; Hines et al. 2010). However, this study covers the neglected area of medical device regulation in a developing country by providing an in-depth analysis of the conditions and processes involved in evolution of Indian medical device regulation and its impact on the local market, firms and access.

2.1 Medical device regulation: a neglected but critical element of healthcare policy
The medical devices sector includes a huge variety of products ranging from medical gloves, bandages to dialysis equipment, baby incubators, and heart valves. There are more than 10,000 major categories of medical devices and diagnostics worldwide (WHO, 2010) including any instrument, implant, machine, intended to be used, alone or in combination, for one or more specific purposes such as diagnosis, prevention, monitoring, treatment, or alleviation of disease (Shah and Goyal, 2008). Medical devices play an increasingly central role in clinical practice, improving patients’ health and quality of life. Yet, Altensatter (2010) argues that the regulation of medical technologies is one of the most neglected areas in the National Innovation Systems (NIS) literature, Development Studies research and Science and Technology Studies (STS). The significant growth of the medical device industry and consequent increased development and availability of sophisticated, costly devices creates a need for more research.

Regulatory systems for medical devices have an important role in promoting technological innovation, facilitating market access and ensuring protection of public health; regulation is as much about risks as it is about markets and companies (Altensetter, 2012). The medical device industry has witnessed significant growth (US $85 billion in 2001 to US$146 billion in 2009 (Kruger and Kruger 2012), revealing increased scale and scope of use in patient care and markets across the world. New market entrants are a key factor in driving this large growth and Sorenson (2015) suggests that along with the higher number of new devices, underlying technologies and knowledge have become more complex. Medical technologies involve combination of knowledge bases from diverse disciplines such as design, material engineering, medical biology, pharmacology and physiology and primarily incremental type, resulting from clinician insights rather than laboratory exploration (Von Hippel, 1988), creating distinctive challenges for devising optimal regulation. This makes the regulation of medical devices a vast and rapidly evolving field that is often complicated by legal technicalities.

In advanced countries the early models for medical device regulation were based on drug regulation before splitting off from it. The inherent differences between drugs and devices make uncritical application of drug regulatory model for device governance significantly challenging. The performance of medical device depends not only on the device itself but also how it is used. Significantly, the intended primary mode of action of a medical device on the human body, in contrast to that of medicinal products, is not metabolic, immunological, or pharmacological, requiring a different set of regulation compared to pharma-biotech products. These differences led to evolution of a legally autonomous medical device regulatory framework starting with the United States in 1976, which was gradually, strengthen with four major amendments in 1992, 1997, 2002 and 2007. This strong link between drug regulations with medical device regulation indicates path-dependent developments and interpretations are at the core of each medical device regulatory framework.

Medical devices around the world are classified based on their safety requirements 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 extent of scrutiny of medical devices is based on the risk class attached to their use. Low risk devices are assessed by manufacturers while in case of high-risk devices significant evidence is needed for their evaluation. This evidence includes criteria on efficacy and safety associated with the device however in case of devices clinical effectiveness (when a device produces the effect intended by the manufacturer relative to the medical conditions) is challenging to prove. This process involves extensive pre and post market studies. All approved devices have to undergo review and assessment to ascertain their benefits and risks to public health before being marketed on the health care system. The different comparative studies of the medical device regulation in advanced regions show that the United States, the Europe and Japan have adopted different regulatory processes, governance structure and evidence requirement for approval of devices (Sorenson and Drummond, 2014). Despite these differences the regulatory framework in these regions share same objectives: to ensure a level playing field for global trade and access to liberalised markets, to enhance human well-being, and to secure health promotion (Altenstetter, 2012).

This review illustrates the dominance of studies focused issues of risk and society in advance region. To date very little attention has been paid to understand the evolution of medical device regulatory systems in emerging country contexts and its impact on the development of local manufacturers and affordable healthcare. In case of developing countries medical device regulation has remained a significant challenge for policy makers and industry. According to WHO, (2013) 53% of low-income countries (18 out of 34 low income economies) and 45% countries in Africa have no regulatory authority. Evidence suggests that ignorance of medical device industry along with lack of resources and capability has resulted in absence of regulation in significant number of developing countries. More research is needed to assess and understand the evolution of regulatory approaches for devices in the developing countries and this paper tries to fill that gap.

2.2 Key conditions and processes shaping medical device regulations in advanced regions

Due to their influence and leadership, the European Union (EU) and the United States medical device regulation have been the focus of attention in academic research (Kramar et al. 2013; Lobmayr; 2010; Kahan, 2009; Sorenson and Drummond, 2014; Chai, 2000, Altenstetter, 2012). This research reveals the emergence of innovative technologies, a globally operating industry and locally delivered healthcare as key drivers of medical device regulation (Altenstetter, 2014). More significantly it identifies the strong government-industry linkages and global harmonisation agreements as key processes that drive and shape the medical device regulations in advanced countries.

‘Medical-Industrial Complex’: Key role of government - industry linkages

Effective government-industry relations are identified as essential elements of innovation systems and significant contributor to shaping of regulations in pharma-biotech industries (Watkins et al., 2015). Focusing on MDI, Nadvi (1999) demonstrates that industry associations not only mobilise collective response to government regulatory policies but also help the policy implementation process among firms. Analysing MDI regulation processes in advance countries, Altenstetter (2012) notes that two teams of players are typically engaged in bargaining, negotiating and solving conflicts and regulatory issues in the international, regional, and national arena. One team consists of the United States-led medical-technology industry (Kruger 2005) and global device companies which, at least in the high-risk medical device markets, have come to dominate and are the most successful in terms of approved
medical device innovations, profitability, and sales (Lobmayr 2011). The influence of device companies is reinforced by the relevant industry associations: AdvaMed in the United States; Eucomed and other EU-based trade associations in the EU; and the Japanese Federation of Medical Device Associations (JFMDA). At the helm of the other team of the regulatory process are the respective regulatory authorities such as USFDA, PDMA (Pharmaceutical and Medical Device Agency, Japan) and EMA. These two teams seek out scientific expertise occasionally in-house but more frequently from out-of-house professional/scientific and industry experts who serve on different advisory committees and provide the scientific input to the regulatory mission. Hancher and Moran (1989) suggests that these three constituents represent the ‘medical-industrial’ complex of the regulatory space of medical device regulation, indicating the regulation of medical devices is as much as about risks as it is about markets and companies (Altenstetter, 2012). Emphasising significance of industry-government linkages, Tan (2012) reveals that in 2012, owing to pressures from various trade organisations (the Tokyo-based AMDD, the JFMDA, the US-based AdvaMed and the European Business Council), Japan is considering a legislative proposal that would separate medical devices from the Pharmaceutical Affairs Law. This confirms the importance of government-industry linkages in shaping medical device industries regulatory framework adopted in the advanced countries.

**Influence of global harmonisation agreements**

With their power and status, the EU and the United States have emerged as strong influence and a driving force for global harmonisation of medical device regulations all over the world. Some of the developing countries such as Mexico, Brazil and others have set up regulatory framework based on the USFDA and the EU directives. These regulatory regimes contain common structural features that concerns with safety and effectiveness of the devices. The advanced countries are also pushing for harmonisation of medical device regulations around the world. For example, to achieve uniformity in the national medical device regularity systems and to improve access to safe and effective medical devices, the Global Harmonisation Task Force (GHTF) was conceived in 1992 by the European Union, the United States, Australia, Japan and Canada. In 2011 GHTF was ceased to exist and replaced by the International Medical Device Regulators Forums (IMDRF) with the aim of ‘accelerating international device regulatory harmonisation and convergence’. However, this drive for global harmonisation seriously neglects the significant role of nation states and national authorities have in devising regulatory framework that is suitable for local conditions.

**3.0 Research Methodology**

This research addresses conditions and processes associated with the evolution of regulation and its impact on capabilities of local manufacturers and health systems in developing countries. In this endeavour the evolving Indian medical device regulation and its impact on the growth of the domestic firms and affordable healthcare provide the appropriate setting. This research employs historical analysis methodology to map and understand significance of key events and role played by different stakeholders in shaping evolution of Indian medical device regulation. We divide the evolution of the Indian medical device regulations into three distinct phases and collect data to understanding the role and influence of different actors, the key processes of interactions between different actors and the prevailing political and economic context in each phase.

Each phase had significant impact on the development of technological capabilities in the Indian firms and accessibility of devices for low-income population. To explore the impact of this evolving medical regulation on technological capability development we categorised our
Data into two broad themes: impact of regulation on factors lying inside the firm; and external to the firm. This interaction between evolving regulation and technological capabilities is further explored by focusing on Indian medical device firms, which were involved in indigenously developing devices for the Indian markets.

Data collection was carried out in two phases. The first phase involved semi-structured interviews with key stakeholders associated with the medical device industry with the aim of understanding key events that shaped the evolution of medical device regulation, role played by different stakeholders and impact of this evolving regulation on access to affordable healthcare. The participants for first phase 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 the Indian medical device association and a government official working with Drug Controller of India (DGCI). In the second phase firm level data collection was carried out and involved interviewing the Head of R&D and the CEO or Managing Director of the firm. We interviewed senior management in the Indian medical device firms such as Shushrut-Adler, Medived, Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST) to grasp the nature and impact of regulatory changes and challenges. Interview questions focused on the current status of the Indian medical device industry, regulatory framework, key challenges it raised for the firm and its impact on the development and marketing of the chosen product. Open-ended questions and a relatively unstructured interview schedule were used to encourage participants to speak in their own words about their experiences, observations and opinions.

We analysed the empirical evidence by using various analytical techniques such as pattern matching (Yin, 1994) and building of analytical tables (Miles and Huberman, 1984). In this research, a strategy of pattern coding is used to identify key events, conditions and processes involved in evolution of ineffective medical device regulation. The review of processes and conditions associated with the medical device regulation in advanced countries highlights it as an evolutionary and path dependent process shaped by government-industry linkages and global agreements (Altensetter, 2012). In this research these conditions and processes provides main themes for the pattern coding and formed a key part of the data analysis strategy. In the second level patterns corresponding to impact of evolving regulation on technological capability development and access to medical devices were identified. In both levels the replicating patterns were supplemented by secondary data that was collected from various sources such as industry journals, industry association publications and annual reports of firms.

4.0 The Indian medical device industry
The Indian medical device industry is estimated at US $ 4.5 bn in 2012 and growing at the rate of 14% per annum (WHO, 2012). The industry is highly competitive and fragmented; there are more than 800 domestic firms primarily manufacturing low technology products such as disposables/ medical supplies while MNCs dominate the high-end medical devices market. The Indian medical devices industry forms a very small part of the total manufacturing accounting for only 0.2% of all certified facilities (Deloitte, 2010). 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. According to Deloitte (2010) the key categories of items that are imported into India include imaging equipment, pacemakers, orthopaedic and prosthetic appliances, breathing and respiration apparatus, and dental equipment. Prof. Valiathan highlights the social cost of import dependence,
the imported items are 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.

(Nagarajan, 2013)

Over the years the domestic medical device industry has struggled with issues of quality and struggled to gain trust and market acceptance in the high-technology segment. Kamath (2010) highlights this link between quality issues and growth of the industry,

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.

(Kamath, 2010)

The current state of the Indian medical device industry raises questions about the evolution of regulatory policy and its impact on the technological capabilities. The next section presents the evolution of the Indian medical device regulation along with role of key events, conditions and actors in shaping the current regulatory quagmire.

The Indian medical device regulation has evolved through three phases (Table 1).

**Table 1 Key milestones in the evolution of Indian medical device regulation**

<table>
<thead>
<tr>
<th>Years</th>
<th>Key events</th>
<th>Phases</th>
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<tr>
<td>2015</td>
<td>A comprehensive draft National Medical Device Policy (NMDP-2015) has been issued and it contains provisions for medical device regulatory authority</td>
<td>Phase III</td>
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<tr>
<td>2013</td>
<td>Amended Drugs and Cosmetic Act is introduced in the parliament</td>
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<td>2009</td>
<td>CDSCO establishes autonomous GMP for regulations of medical devices</td>
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<td>2008</td>
<td>Parliamentary committee rules against establishing central authority, object to the clash of views between the MoHFW and the DST on the issue of regulating medical devices, DST issues updated Medical Device Regulatory Bill</td>
<td>Phase II</td>
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<td>2008</td>
<td>MoHFW &amp; DST proposed two independent bills</td>
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<td>2007</td>
<td>Legislation is drafted to develop central medical device regulatory authority, but no progress is made</td>
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<tr>
<td>2006</td>
<td>FICCI, AdvaMed, CII starts working with govt to frame appropriate medical device regulation</td>
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<tr>
<td>2006</td>
<td>Indian government brings 10 devices under the Drugs and Cosmetics Acts (1940), later 4 more devices added to the list.</td>
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<td>2005</td>
<td>60 patients were harmed in hospital due to use of imported stents and high court orders government to set standards for devices</td>
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<tr>
<td>2003</td>
<td>Mashelkar committee publishes report calling for establishment of medical device regulatory division in CDSCO</td>
<td>Phase I</td>
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<tr>
<td>2003</td>
<td>ICMR expert committee publishes report calling for central medical device regulatory authority</td>
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1990 | Indian government liberalises economy and gradually reduces import duty, leads to increasing import of medical devices

1980 | Indian government intends to frame medical device regulations but due to no progress is made

### 4.1 Era of regulation vacuum (to 2005)

From independence till 2005 there was effectively no quality regulation for medical devices - whether imported or manufactured in the country. Manufacturers of low-tech devices such as thermometers and weighing instruments sought optional certification (ISI marking) from Bureau of Indian Standards (BIS) as a proof of quality but not as a pre-market approval requirement. BIS certified and regulated a few other low technology devices. Due to their limited scope and depth, these standards and procedures were not adequate for high technology devices.

In the pre-2005 era imported high technology devices approved by the country of origin or by the USFDA were permitted for marketing in India. However, there was no regulatory mechanism to check certification of the products or product quality. For instance, in 2004 Boston Scientific and Johnson & Johnson withdrew sale of one brand of its cardiac stents worldwide, but no independent information was available in India on how many of these devices may have been used or if any patient had reported any adverse event (Harper, 2003). During this period the medical device sector stayed under the radar of different industry associations, civil society organisations and remained unrepresented at the government level. Some experts point to the small size of domestic MDI and the low-tech nature of devices as main reason for the overall neglect of the industry. Dr Valiathan comments,

> Pharma was established in India for decades; their R&D picked up momentum after India signed the WTO agreement and patent regime changed. Biotech had novelty and glamour and government set up a department, which promoted it aggressively. Devices suffered from neglect by the medical profession, technologists, industry and government. Poor investment in R&D facilities and absence of 'Medical Device legislation' is hampering growth of the Indian medical device industry.

(Interview data)

In the early 1980s the government did realise the need for medical device regulation but limited understanding of how medical devices work, mechanism of action and criteria for performance measurement hindered further progress. A biomedical engineer with Sree Chitra Research Institute comments,

> The point was 1980, the year I joined the institute. Prof. Valiathan and I started working on the biomedical device act but it all go stalled in the end. There was no interest or understanding.

(Interview data)

Post 1990s the economic liberalisation fuelled the growth of the Indian healthcare market and that gave boost to domestic firms, increased imports of devices and brought additional scrutiny from domestic and international civil society organisations. Taking cognizance of the increasing demand for medical devices and absolute dependence on imports to satisfy that demand, the Indian government significantly reduced import tariffs on medical devices to the
range of 15 to 30% and de-licensed imports. This resulted in significant growth scale, size and scope of imported devices. However, in absence of credible regulation, Harper (2003) argues that in some categories inferior quality products were imported and used for treating low income populations in India. There were no regulatory guidelines and control on how device actually works, its technical specifications and performance. There was little information available on medical devices apart from that provided by firms for marketing purposes. During this period medical devices were sold in India without any monitoring by regulatory authority or reporting by hospitals. With the exception of few, majority of domestic firms were comfortable with absence of regulation and made no strong demand for it. A leading orthopaedic equipment manufacturer points out,

In medical devices multiplicity of technologies that usually brings one solution and thereby validation of devices is a very expensive exercise. In non-regulated environment like India, you had companies that were not bothered about regulation because there was no regulation and nobody was asking for it. So these companies thrived in giving something cheap even without bothering to take tests if it is right. For example, a representative of MNC went to Ludhiana to source a key product and he found that manufacturing unit was actually a cowshed where they were making this product. That’s why the local lobby did not want any restriction.

(Interview data)

This lack of specific regulation for medical devices created significant obstacles for innovative domestic firms involved in indigenous R&D. For example, Sree Chitra Research institute struggled to launch indigenously developed heart valve, as there was no clear authority that was responsible for approval of high-tech medical devices developed locally. In the absence of local regulators, the scientists working on heart valve project decided to get the product tested with the USFDA. A senior engineer associated with heart valve project explains,

In India there are some islands of excellence in different medical device verticals. What these companies decided that they want to be international in their approach and adopted methodologies that are international. Due to absence of local regulation these companies went overseas to USFDA approvals, or CE certification. My product was CE certified five years before the local regulation came into practice.

(Interview data)

However, getting international approvals affected completion project, further delayed the launch of product in the market and increased cost of product development. Acting on regulatory vacuum, the Indian Council of Medical Research (ICMR) established an expert committee and in 2003 this committee released a report on setting up of the ‘Indian Medical Devices Regulatory Authority (IMDRA). This report highlighted the need for regulatory authority, describing the prevalent regulatory situation as,

The R&D efforts can benefit the country only if the final products are made available to the people through Good Manufacturing Practices (GMP) and well-regulated marketing procedures. Unfortunately, no such procedure exists in the country for high-tech devices. It appears that some imported high tech devices, approved by the country of origin or by the FDA, are permitted for marketing in India. As on date no regulatory mechanisms exist even with the Drug Controller General of India (DCGI) for certification, quality assurance and post market surveillance of both imported and
indigenous medical devices. Obviously, neither any regulatory body has been entrusted with this responsibility nor a new organisation has been created, leaving the quality assurance and regulation of medical device in vacuum. The practice being followed, as DCGI is to refer the matters related to biomedical devices to ICMR (Indian Council of Medical Research) on case-to-case basis.

At the same time another high profile report on drug regulation also highlighted regulatory vacuum for high-tech medical devices. In 2003 the Indian government set up an expert committee headed by leading scientist Dr Mashelkar to examine drug regulatory issues, including the problems of spurious drugs. Going beyond the remit of drugs, the Mashelkar committee report called for setting up a separate division in Central Drugs Standard Control Organisations (CDSCO) for regulating imported and domestically manufactured medical devices. However, the Indian government took no action on the committee recommendations as it was deemed to be a no-priority area (interview data).

In 2004 neglect of regulatory infrastructure resulted in a serious incident at Jamshedjee Jeejeebhoy (JJ) Hospital in Mumbai. The JJ hospital used unapproved drug eluting stents on 60 high-risk cardiac patients. Stents were manufactured by Netherland based company and were not approved for use in the EU markets. Taking cognisance of public outcry government shut down the importer and a local company. However, both importer and a local stent company went to court showcasing the absence of regulations. In 2005 the Mumbai High Court discussed the case and ordered the Indian government to set rules and standards for the medical device industry. This started ‘a chain of knee-jerk reactions’ from government that resulted in setting up of ambiguous regulation (Interview data).

4.2 Era of ambiguous regulation (2005-2008)

In March 2006 taking cognisance of JJ Hospital case and Mumbai high court order the Indian government listed 10 medical devices to be regulated in an amended Drugs and Cosmetics (D&C) Act, 1940. These devices required a license to manufacture, sell and distribute. But no other devices whether imported or manufactured in the country, were regulated. An orthopaedic implant manufacturer explains,

At that time there two parallel things that happened. Department of Science and Technology had created what was called Medical Devices Safety Bill, which had recommended creating a separate Medical Device Regulatory Authority, MDRA, as they called it. Prof. Valiathan and group were involved in this. This work was happening when this JJ controversy came up and the high court order government to regulate to medical devices. They had no data or framework to regulate with and you need a lot to regulate. So at that time instead of passing a correct comprehensive law, what government did, they chose the route of notifying 10 devices as drugs under D&C without understanding what they are doing. That is how we have landed up in this mess.

(interview data)

The Drugs and Cosmetics Act 1940 is the major source of pharmaceutical regulations in India and applies to all products whether local or imported. The primary objective of the Drugs and Cosmetic Act is to ensure safe and effective healthcare by regulating the import, export, manufacture, distribution and sale of drugs, cosmetics, and conduct of clinical trials. The amended act now included jurisdiction over “devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or
animals, as may be specified from time to time by the central government". The Indian
government set up this amendment with two primary aims: first, to improve accessibility of
safe and effective devices and second, to support local manufacturers by creating a regulatory
framework for notified medical devices. Table 2 details the arrangements that emerged from
the amendment to the Drugs and Cosmetic Act.

Table 2 Current status of medical device regulation in India (WHO, 2012)

<table>
<thead>
<tr>
<th>National Regulatory Authority</th>
<th>Medical device regulation in India</th>
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<tr>
<td>Central Drugs Standard Control Organization (CDSCO) in the Ministry of Health and Family Welfare (MoHFW)</td>
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<tr>
<th>Risk classification system Requirements for registration/ importation</th>
<th>No risk classification system</th>
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<tbody>
<tr>
<td>Only certain categories of devices require registration</td>
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| Vendor registration/ licensing | Indian authorization agent holding 20B and 21B licenses required for registration, vigilance and inspection activities |

| Recognized certifications/ approvals | Registration in US, EU, Japan, Canada or Australia can fast track the review process |

| Quality system requirements | Must comply with quality system standards of country of manufacture |

| Medical device labelling | Indian Standards Specifications by the Bureau of Indian Standards |

Soon it emerged that there were serious problems with regulation of medical devices under
the Drugs and Cosmetics Act. Increasingly medical devices firms operating in India began to
experience inconsistent application of the current guidelines causing renewed confusion and
delays. These problems resulted in part from 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 the CDSCO (the US trade report, 2010). Some respondents point out that the domestic
and international device manufacturers were assured that these regulations would not be
stringently enforced with acknowledgement from regulators about lack of clarity and absence
of capability to manage increasing number of application. In practice, the regulation was
implemented inconsistently, and with errors, by multiple authorities.

Some companies struggled to get licenses for products for more than 6-7 months even when
they had been on the market for more than two decades and had received regulatory approval
for their products from overseas regulators (Kamath, 2007). Several experts concluded that the regulatory framework and infrastructure designed to govern pharmaceutical and cosmetic products was totally inadequate for governing medical devices due to the nature of difference in products, their action in human body and packaging. For example, concept of sterility differs in pharma-biotech products and medical devices. A drug has to be manufactured in ‘clean room conditions’ requiring certain kind of flooring, air-flow and energy requirement to minimize impurities. In contrast, medical devices can be sterilised at the point of use, even in the operating theatre and doesn’t require the same production conditions. For instance, an orthopaedic surgeon orders different sizes of implants from the company and at the time of surgery sterilises only those which fit patients. A head of Indian diagnostic company suggests,

The main pain point for medical device sector is that it is clubbed with pharma sector and treated like that. There is this fundamental issue. We went to the government, lobbying that medical device sector should be treated as a separate sector. It should not be a part of D&C act. And that’s the reason why you find a lot of confusion.

(Interview data)

In the amended law there was no regulatory mechanism for certification, quality assurance and post marketing surveillance of imported and locally made medical devices except for the notified devices and diagnostics. Many of these devices are sterilised using various techniques, efficacy of which need to be validated and current regulation fails to do so. These problems started to affect the availability of medical devices. Increasing pressure from industry association and complaints from patient groups forced the Indian government to act to improve the regulatory situation. That led to the drafting of the new amendment in 2007 aimed at improving medical device regulation and setting up a centralised regulatory authority. Soon this legislation ran into trouble due to lack of expertise and understanding within the government. An official with industry association highlights it as a key issue,

In the government, expertise to deal with the medical devices is not there. So if you look at the DCGI, DCGI inspectors are basically pharma inspectors. They don’t have the expertise on the medical device technology. Whatever rules they apply for drugs, they are applying for devices. But entire principle is different. It’s a completely a different ball game. You are talking about pricing, you talk about bar coding and so on. All regulations that are in place for drugs, now they are applying for devices.

(Interview data)

During this period the Department of Science and Technology (DST) and Ministry of Health, Family and Welfare (MoHFW) put forward two independent proposals, with DST suggesting the Medical Devices Safety Bill, 2008, as a comprehensive regulatory framework for medical devices and MoHFW arguing for establishment of a Central Drugs Authority (CDA) covering all regulated healthcare technology products. An official with industry association comments,

So there are two choices; Medical Devices Safety Bill which can get reactivated and this, in which within the drug authority a separate medical device regulation.

(Interview data)

Both these proposals shared two common objectives: regulatory regime that distinguishes between pharmaceuticals and devices and adequate powers to ensure standards, efficacy, safety and availability of medical devices manufactured or marketed in the country. But they differed in the proposed governance structure required to achieve that. MoHFW proposal had
the CDA structure resembling the regulatory model used by the USFDA; a central body responsible for regulation, licensing, surveillance and monitoring of medical products and the uniform implementation of laws pertaining to medical devices within the country. It would collect fees for permission to conduct clinical trials for drugs, devices and cosmetics. The CDA would classify devices, notify standards and guidelines from time to time, provide a mechanism for conformity assessment using direct or third party notified bodies and stipulate the procedure and guidelines for testing laboratories. In contrast, the DST proposal suggested adoption of a more de-centralised structure based on the governance framework adopted by the EMA. These differences led the Indian government to form a parliamentary committee in 2008, which came up with an alternative approach. The committee suggested amending Drugs and Cosmetic Act of 2007 to facilitate formation of a financially self-sustaining regulatory body using the existing structure (DCGI/CDSCO) to handle administration of medical devices regulation without creating a big, new infrastructure or encroaching on many of the responsibilities of other existing bodies. Based on the belief that it is not feasible to remove existing institutions, the committee recommended against establishing the CDA at this stage (interview data).

The parliamentary committee brought the focus back on the Mashelkar committee report by supporting one of its recommendation of restructuring, strengthening and modernizing the existing CDSCO under the MoHFW that will oversee a centralized licensing system and maintained a network of offices at the zonal and sub-zonal levels. Although all three proposals were unanimous about the inadequacy of the existing regulatory systems, they all differed on the governance system that should be adopted. The Parliamentary committee did note delay in achieving appropriate regulation and linked it in part to the clashes and differences in approaches by the DST and the MoHFW.

The Parliamentary Report involved more than one year of studies, consultation and negotiation with different stakeholders such as industry association, civil society organisations and industry experts (the US Trade Report, 2010). By 2008 the Federation of Indian Chambers of Commerce and Industry (FICCI), one of India’s leading industry associations, took up this issue and emerged as a focal point for framing the regulations of medical device. FICCI along with AdvaMed and medical device firms (local, importers and MNCs) started to work closely with the CDSCO and MoHWF to devise appropriate regulations that can aid access to medical device, promote local production and streamlined the regulatory process towards global harmonisation. In late 2008 the Parliamentary Committee report was presented in the upper house of the Indian parliament and in December 2008 the MoHFW renewed re-drafting of the legislation as per the Parliamentary Committee’s recommendations. During this period medical devices manufactured and imported in India continued to be monitored under a wrong and confusing regulatory structure. It became apparent that those regulations specific to the India medical device industry are somewhat limited and lacked clarity and transparency, while low internal quality standards contributed to wide quality variances among products on the market. One leading diagnostic device manufacturer reflects,

Lack of regulation was one big barrier and one of the worst things to happen. Now that regulation has come in, they have come in only for some spectrum of products. But these are also not correct regulation and thereby wrongly implemented by the government. So I don’t know what is worst; not having regulation or having inappropriate regulation. That is completely erroneous thing to do.

(Interview data)
The absence of clear regulations and inconsistent interpretation and application of the regulatory guidelines by multiple levels of government created a prolonged and cumbersome regulatory pathway for medical devices in India.

4.3 New Medical Device Regulation bill: Towards a divergence from drug regulations (2009 onwards)

Eventually, the Indian government realised the need for recognising medical devices as a distinct category in the healthcare industries and in 2009 introduced a chapter on medical devices in Drugs and Cosmetics Act. Under the amended Drugs and Cosmetics Act, regulatory control began to be observed at manufacturer, hospitals and market level and the CDSCO and DCGI in the MoHFW were nominated as central bodies involved in governance of drugs and medical devices in the India. To facilitate administration of device regulation, the CDSCO established two different units: Device cell and Diagnostic cell, responsible for the oversight of medical devices and diagnostic firms. The CDSCO was designated as responsible authority for dissemination of information on registered medical devices, licensed distributors, and compliance. It adopted a divisional structure; with central division responsible for drafting of device standards and regulations of clinical research while state divisions were put in charge of recalls and licensing of manufacturing sites. Along with the CDSCO, the Bureau of Indian Standards (BIS) continues to regulate few other low technology devices. The imported high technology devices, approved by the country of the origin or by the US FDA, are permitted for marketing in India. The importers of medical devices can use their approvals in the US, Canada, Europe, Australia or Japan to register their medical devices in India. In parallel, the CDSCO also devised autonomous Good Manufacturing Practices (GMP) regulations for production of medical devices in India. These guidelines were separate from pharmaceutical sector and under the new rules the manufacturer was required to comply with GMP to gain approvals. This amendment provided key guidelines for local manufacturers on standards required for authorisation of the medical devices and thereby an opportunity to develop devices that can compete with MNC products.

These provisions again proved inadequate. In 2009 different industry associations intensified their effort and in response the Indian government formed the Indian Medical Device Regulatory Review Group (IMDRV) as a forum for the industry, the regulators including the conformity assessment bodies, the testing institutions, and consumer groups to bring around overdue reform. AiMED along with other industry associations made strong representation to the IMDRV group and that led to framing of specific regulations for medical device industries in 2012. The Drugs and Cosmetics (Amendment) Bill 2013 was introduced to upper house of parliament in 2014. This draft provisions laid out are largely in line with standard international practices developed by the International Medical Device Regulators Forum (IMDRF). This new legislation is expected to bring all medical devices sold in India under the purview of the government agency charged with regulating medical devices: the Central Licensing Approval Authority (CLAA) under the CDSCO. However there still remains an issue of appropriateness of these provisions for local contexts and their impact on supporting local innovations. For example, new bill defines adulterated device as any device that is composed of in any measure “rusted or corroded or filthy or putrid or decomposed substance”, packed under unsanitary conditions that would make it hazardous to someone’s health, contains toxic substances, and so on” and puts total responsibility of ‘adulterated device’ on manufacturer. However, the head of medical device industry association points out that device can become contaminated at point of use,
So even if a user stores a device improperly, it’s the manufacturers who will be held liable. That’s not all. The bill talks about minimum standards for medical devices, but doesn’t actually define what these standards are. These devices are pieces of science and engineering. You can measure the efficacy of drugs, but not of a medical device. The government should measure their performance. Drugs and medical devices are two completely separate things. You can’t measure them with the same indicators (Nagarajan, 2013).

The Indian government is still working toward establishing a medical regulatory regime that can distinguish between devices and drugs but struggling to set up governance structure that will satisfy different stakeholders. The head of Indian industry association comment, FICCI was first association to take proposal to government that devices and drugs need a different formulation. We have been going back and forth. Government says new bill is going to take time. But new bill doesn’t include what we are suggesting; that it should include a separate chapter for devices. After all we worked very hard with the health ministry to actually come up with the rules. But that is stuck in parliament, which is beyond our control. (Interview data/2015)

Further, new medical technologies and global markets require continuous reform of the respective regulatory framework and increasingly tailor-made and product-specific regulation. This clearly indicates that the Indian regulator needs to set up a different autonomous department that can work with companies, clinicians and hospitals. A senior official of a leading industry association suggests,

We are working with department of pharmaceuticals to create a separate division for medical devices and have a separate regulator. That way you can start building expertise. Existing situation of a regulator for devices working under the DCGI is not the best way forward. You need to have a third party, standalone regulator like you have for telecom, insurance and finance sector. Its important that regulator should be independent and should be equivalent to secretary of India, reporting directly to minister rather than joint secretary. (Interview data)

This description of evolution of medical device regulation highlights the conditions and processes that led to the emergence of ineffective medical device regulations in India. These different phases regulatory evolution had a significant impact on development of local production capabilities as well as ensuring access to affordable devices to local population. Evidence suggests that this regulatory ‘quagmire’ is making it hard for local manufacturers to create credibility for their products in the market, breeding distrust among the investors who may be interested in funding these products and discouraging MNCs planning to set up new R&D and manufacturing facilities.

5.0 Analysis and discussion
The description of the evolution of medical device regulation reveals that serious communication gaps between industry and government, between different government departments and knowledge gaps among policy makers in understanding needs of the medical device sector has contributed greatly to the development of ineffective regulation in India. In
turn, this regulatory environment had a significant negative impact on the development of local technological capabilities and availability of affordable medical devices in India.

5.1 Conditions and processes involved in the evolution of medical device regulation in India
As with advanced country medical device regulations, Indian medical device regulation has strong roots in drug regulations. However, in India the process of divergence from the drug regulation and the development of autonomous medical device regulations proved a challenging process.

Policy fragmentation within government
The lack of communication and policy coherence among different departments within the government and their areas of jurisdiction have created significant complications in developing an appropriate regulation. A head of leading industry association points out,

So today we are saying simplify the regulation, why do we need to report to five ministries and none of these ministries talk to each other, they are all asynchronous in these ministries… the whole thing is they are just not working in unison and nobody know all the aspects when they are taking decisions on a certain subject.

(Interview data)

Post 2005 the legislation for governing medical devices has undergone a number of different drafting stages during which time the MoHFW and DST repeatedly clashed on the governance mechanism and debated number of issues with limited results (interview data). Up to certain level this policy fragmentation is expected but its extent resulted in the situation where governance of the medical devices is till in flux. There is a still strong knowledge gap among different policy makers on the precise regulatory needs of medical device industry. Expressing frustrations at the pace of changes, an emerging entrepreneur of a diagnostic firm suggests,

We are trying to create awareness but it’s not coming easily. It takes time to move things which has been settled for so many years. We were so small that we became invisible for the government.

(Interview data)

Weak government-industry linkages
In developing countries, the importance of industry associations in the transfer of global knowledge on standards and practices to the national and local level is well established (Papaioannou et al., 2016). In early days absence of a strong industry specific association representing interests of medical device domestic and MNC firms proved to be a major barrier, preventing institutionalised communication and exchange of ideas between these two government and industry. An official with the industry association suggests that competing interests of domestic industry with MNC proved a major hindrance,

When you say 70% of the business is done by MNCs who do not have domestic manufacturing, by imports, there is a very strong need to sustain those imports. Thereby, to have an industry body which will talk in one voice to sort encourage domestic industry is no reality today. It will not happen. In the med-tech industry as opposed to car industry, it becomes a little difficult to convince why you should stop free imports.
This gap in communication will filled up by the civil society organization and active intervention of the judiciary. This ceding of political space to civil society organization and judiciary forced governments towards framing of the regulation without requisite expertise and understanding. This led to adoption of wrong regulations and made industry to enter the consultation process with the government. After that both the domestic and international industry association became fully involved in the process and the Indian government generally been receptive to participation by private sector stakeholders. A head of orthopaedic company suggests,

> In the beginning it was a chain of knee-jerk reactions. Now of course government authorities understand what is needed but it’s been five years since the wrong regulation. We have been involved in making them understand so the central office understand what is needed but now we are waiting for the amendment of drugs act in which they will define medical devices independently and appropriately.

The U.S. medical device trade association AdvaMed working with the local American Chamber of Commerce (AMCHAM), Confederation of Indian Industry (CII), and the FICCI has provided the Indian government a considerable amount of information and suggestions on ways to improve effectiveness of proposed medical device regulations. The involvement of the Indian industry associations along with the U.S. medical device trade association, AdvaMed lobbied with the Indian government to align with harmonized international guidance and consistent with established regulatory systems of the advanced countries.

5.2 Impact on development of Indian medical device sector
The evolving regulatory framework had significant impact on the development of the Indian medical device industry. It severely handicapped local manufacturers by hindering predictable access to market, led to emergence of market dominated by expensive MNC products and counterfeit devices and severely limited growth of collaborative network of firms and research institutes.

**Handicapped innovative local manufacturers**
The evolving regulatory process created a significant hurdle for local manufacturer to develop products locally and enter the domestic as well as international markets. Regulatory approval process for high-tech products was highly ad-hoc and in many cases the local innovators had no idea whose approval they should take to launch product.

The struggle for domestic companies is well evident in example of Sri Chitra Research Institute. Murthy (2004) points out that from 1994 to 2004 more than 11,000 valve procedures were done per year in India, but only 1,000 valves developed by the Sri Chitra Research Institute were used even though they cost less than 50% of the average of imported valves. The Indian clinical community is averse to using devices of the local manufacturers because of uncertain standards and lack of quality assurance.

**Monopoly rent: MNC dominated domestic market**
Without proper authorisation, the local manufacturer struggled to gain acceptance for their products in the domestic market and often fared poorly against MNC products, which were approved by the western regulators and backed by huge amounts of clinical trials data.
Absence of local competition and total dependence on imports gave MNCs monopoly power over the Indian domestic market. MNCs sold their products in the Indian market without really taking into consideration of production cost or purchasing power of local populations, as there were no local competitors creating pressure to reduce prices and no regulation to monitor their profit margins. Thus the total lack of regulation created skewed market in favour of MNCs and as a result these companies could charge ‘monopoly rent’. This skewed market created immense problem for securing access of affordable devices for local population.

Further, MNCs were primarily involved in the distribution of medical devices and seek to enter the domestic market either by employing local agents as distributors or setting up sales and distribution presence.

Mushrooming of counterfeit products and manufacturers
The lack of regulatory oversight resulted in the industry populated by spurious operators and counterfeit traders who used scrap material as raw material or import goods of uneven quality from overseas manufacturers. Many small trading companies importing unregulated products from China, Korea and Taiwan at a very low rate, even lower than Indian firms’ production cost mushroomed in the country. The market is flooded with non-standard look-like counterfeit products, which are sold at very low prices. Many of medical devices are implanted into the human body for critical care. Implantaing 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 they were main recipients of cheap counterfeit and unsafe medical devices.

To conclude, the evidence presented here suggests that the Indian medical device sector was totally un governed from 1947 till 2005 and the period witnessed abysmal growth in local industry. The domestic market was ruled by unaffordable devices from MNCs and swamped by counterfeit products from spurious local traders. In absence of local regulation, authentic Indian device developers and manufacturers suffered the most as they struggled to gain acceptability of their products. The combine effect of this situation resulted in exposing low income population to unsafe devices and restricting their access to affordable medical devices. Post 2005 the development of medical device regulations proved a challenging process for the Indian government with the lack of cohesion among different government departments, weak government-industry linkages and increasingly active role of civil society organisations and judiciary exerting influential role in shaping process and outcome.

6.0 Conclusions
This study is the first to provide an in-depth analysis of the conditions and processes involved in the evolution of medical device regulations in a developing country, their impact on the local market, firms and popular access to devices. It does this by studying the development of ineffective medical device regulation in India. It reveals the existence of communication gaps between industry and government, between different government departments and gaps in understanding the needs of the medical device sector among policy makers as a key contributor to ineffective regulation in India. The resulting regulation has had a significant negative impact on the development of local technological capabilities and the availability of affordable medical devices in India. These findings have implications for other developing countries. In short, stakeholders should ‘mind the gap’ and make concerted efforts to bridge this ‘gap’ to avoid regulation quagmire and arrested development.

Similar to Scoones (2003:3) reflections on regulation in the agri-biotechnology sector, this research “raises a number of different perspectives, both challenging, and importantly,
broadening, the framing of the debate from one of a narrow, “back end” concern with risks and technology impacts to a much wider “front end” discussion about inclusive development. It indicates that the stakes involved in steering of life sciences industries are very high and actors who are involved in steering needs to have a good understanding of technology – regulation interactions and its implications of affordable healthcare. In some circumstances it is certainly possible that policy makers may not have complete understanding of emerging technologies and this ‘gap’ can negatively impact on growth of the sector but as evidence based on medical device regulations in advanced countries shows, this gap is bridged by stakeholders such as national and international industry associations, consultants and experts (Altenstetter, 2012). The two-way communication between industry and government has helped policy makers to understand the regulatory needs of the evolving technology and set up appropriate policies. In case of the Indian medical device industry absence of a strong medical device industry association has proved to be a major barrier, preventing institutionalised communication between these two key stakeholders. In addition, the small size of Indian medical device industry and lack of innovation ecosystem further limited local expertise and compounded challenges of framing appropriate regulatory framework. This analysis shows that the state, even though the most important planning institution, doesn’t have all expertise, bringing into sharp focus of other institutional actors such as industry associations, civil society organisations and judiciary. These different actors collaborate or oppose with each other in effort to achieve optimal policy to suit their objectives. Further, different government departments work with their own policy objectives and these fragmentations further adds to complexity of the process. The sheer complexity of the policy process and its embeddedness in the Indian political and social life, is revealing and important for any discussion about what appropriate policy responses might be to the regulatory dilemmas presented by healthcare sector in general and medical device industry specifically in the developing world.

This research clearly highlights the significance of appropriate regulation for the development of local industry. Without effective regulation, the local Indian firms faced a significant lack of clarity in terms of regulation and predictable access to market. The local producers had to compete with counterfeit manufacturers, powerful MNCs and local traders who imported devices of unproven quality. This reduced attractiveness of the market and led to limited entrepreneurial investments, which in turn has led to lower investments in building up the component ecosystem and the technology skills base to support this market. This gap between regulatory, industrial and health policies had severe damaging impact on development of local technological capabilities and ensuring affordable healthcare for poor population.

The Indian evidence suggests that, while regulation can create more equitable playing fields, which can be vital for harnessing innovation, not just any regulation will do. Despite the international pressure of uniformity and harmonisation in regulatory policy, this paper shows the fallacy of that approach by highlighting significance of local contexts and how there clearly can be no one-size-fits-all solution. In Indian case there is a clear need of new framework that must place the lack of access to affordable medical devices for majority of population at its heart and in parallel, facilitate the local innovation system by ensuring that local manufacturers are protected from counterfeit products and manufacturers. This indicates that the developing countries should focus on creating regulations that will ensure safety, efficacy and quality parameters that match consumer expectations and are suitable to the local context.

8. References


Cohen, D and Billingley, M (2011) Europeans are left to their own devices. BMJ. 2011; 342:2748.


Deloitte (2010) Medical technology industry in India: Riding the growth curve

Espein, R., (2006) How excessive government regulation stifles pharmaceutical innovation, Yale University Press,


McAllister, P and Jeswiet, J (2003) Medical device regulation for manufacturers, Journal of Engineering in Medicine, 217: 459-467,

Magotra, R. (2006) The controversy of drug-eluting cardiac stents, Indian Journal of Medical Ethics, Jan-Mar, 3(1)


Papaioannou, T; Watkins, A; Mugwagwa, J and Kale, D (2016) To Lobby or to Partner?