

Why Industry Associations Matter for Healthcare Industries in Emerging Countries: Evidence from the Indian Biotechnology and Medical Device Industries

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Abstract

This paper focuses on the often neglected role and potential of industry associations in facilitating growth and development of healthcare industries in emerging countries. Using case studies of the Indian biotechnology and medical device industries, the research presented here shows that industry associations and related umbrella organisations played a critical role in the development of the Indian biotechnology industry, while lack of similar representation created regulatory and industrial policy hurdles for the Indian medical device industry. Early on, biotech industry associations in India were proactive in lobbying the government to set up an appropriate regulatory and technology policy regime and over the years entered into a strategic partnership with government to promote entrepreneurship and affordable healthcare. By contrast, in the case of medical device industry, the diverse nature of products and underlying knowledge bases made it difficult for policy makers to fully grasp specific industrial and regulatory policy requirements. This lack of understanding was further accentuated by the absence of sector-specific industry association, creating a communication gap between government and industry and leading to the neglect of the medical device industry. This research emphatically highlights that 'industry associations' play critical role of plugging communication and information gaps between government and industry, promoting entrepreneurships and diffusion of regulatory policies among its members. The ability of industry associations to reduce transactions costs makes them a critical and indispensable part of national innovation systems in general and healthcare systems in particular.

1. Introduction

The role of industry associations in shaping government policies remains an area of great interests for innovation and industrial policy scholars. In the innovation system literature it is argued that an industry association can act as a key intermediary with the ability to influence emergence and evolution of the industrial sectors (Watkins et al. 2015). Several empirical studies have highlighted the beneficial impact these organisations can have on facilitating the innovation process by performing various activities, which can be categorised as consultant, broker, mediator and resource provider (Nadvi, 1999; Mcmillan and Woodruff, 1999). Industry associations are credited for compensating inadequacies in the business environment by performing an important role of informing government about needs of their members and acting as a nodal point for coordination activities with different stakeholders (Newell, 2003; Faulkner, 2000). Some researchers suggest that a small special interest group through collective action can influence the policy in their favour and provide value to their membership (Olsen, 1999). But these organisations are also criticised quite often for their rent seeking behaviour and working for the narrow interests of their members (Scoones, 2003). It is argued that a small group can distort industrial policy in interest of its members to such an extent that it can become detrimental to other stakeholders, further highlighting issues of power and rents seeking that are associated with the industry associations (Athreya and Chaturvedi, 2007). Although research focused on industrial policy and innovation systems highlights the significant lobbying and intermediary role industry associations' play in capitalist economies in advanced countries, there have been few attempts to explore the role of these associations in shaping policies that can influence growth and evolution of innovative capabilities in developing countries. This represents a critical gap in our understanding of innovation focused policy-making processes in healthcare sectors of developing countries.

In order to close this knowledge gap, this paper explores the role of industry associations in policy processes concerning biotechnology and medical device industries in India. India represents an interesting case through which to understand the role of industry groups in biotechnology and medical device policy process. In case of India the introduction of economic liberalisation and adoption of market friendly policies has given rise to a new form of government-industry interaction. According to Newell (2003:1) in global terms India's size and influence transcends the country's boundaries of the countries as in the sense that 'what happens in India sends out powerful message to the rest of the developing world'. Over the years the Indian biotechnology and medical device industries have demonstrated contrasting growth and innovation trajectories with the biotech sector showing remarkable success while the medical device sector struggling with technological capability development. This provides good case studies to investigate role of industry associations facilitating growth and innovative capabilities in healthcare sectors based in the developing country.

Empirical evidence from this research indicates that biotechnology industry associations and related umbrella organisation played a crucial role in the shaping of biotechnology industry by influencing government's regulatory, industry and trade policies through uneven yet highly productive relationship that contributed to a robust and dynamic Indian biotechnology industry. By contrast, in the case of medical device industry the absence of sector specialised industry association till 2009 and lack of representation from umbrella association significantly hampered the state-industry interactions and led to neglect of the sector, affecting the growth of domestic medical device entrepreneurs. Our research also highlights that further growth of innovative capabilities in the Indian biotechnology industry and development of domestic medical device industry in a way that it will effectively address its local healthcare needs will require greater trust and transparency and complimentary relations between industry, government and civil society.

The remainder of this paper is structured as follows. Section 2 reviews the literature focused on the role and activities of industry associations as intermediaries in innovation systems, along with the potential and challenges that such institutional actors offer in the context of developing countries. Section 3 presents the methodology underpinning this research while section 4 discusses the changing economic and political context along with role of industrial associations in India. Section 5 considers the cases of Indian biotechnology and medical device sectors respectively. Section 6 presents analysis of primary and secondary data based on analytical framework based on innovation system framework. Section 7 concludes by summarising the overall argument; namely that industry associations in developing countries play an indispensable role in communicating needs of private firms to government and their absence have detrimental impact to growth and development of the healthcare sector.

2. NIS and Industry – government interactions

The national innovation systems (NIS) concept highlights interactions between institutions as a central construct for innovation and industrial capacity building (Lundvall, 1992; Arrow 1962). It is highlighted that these interactions facilitate information sharing between several societal institutions and organisations leading to cumulative knowledge and collective action for industrial development and public advancement. Watkins et al (2015) argue that early NIS literature does not sufficiently consider intermediary organisations that work with the state to inform and steer conditions and incentives for innovation and growth within particular industries and technological sectors. In case where intermediaries are discussed, the focus is on network actors such as consulting organisations, venture capital firms and technology transfer offices that connect and facilitate knowledge transfer mainly between firms (Davenport et al., 1999). Papaioannou et al., (2015) highlight absence of industry associations in these discussions and link it to 'omission of politics' from the earlier NIS concept. The interactions between different institutions and collective action include several 'interest' agendas reflecting individual and institutional/organisational differences and the ability of each to negotiate the agenda favourable to its own interests will depend upon the power hold by that individual or organisation. Focusing on the issues of power and politics, Bachrach and Baratz (1962) show that power in the area of agenda setting is multifaceted. They discuss 'two faces' of power: the first is centred in the authority to choose and make decisions; the second is concerned with the ability to influence what issues are considered in the first place. They argue that the second face of power is potentially more important than the first and in this context capability of the industry associations in capitalist economies to influence decision makers is well established. The retreat of the state in economic planning and the adoption of market friendly policies have led to the emergence of lobbying as a significant method for private sector enterprises to influence development policy action. Some researchers have criticised the direct (shaping what gets onto the agenda) or indirect (influencing others who do shape the agenda) influence of industry associations on the policy making process. For example, Athreye and Chaturvedi (2007) point out that small groups can capture power and extract rents at the expense of the rest of the group and society at large; giving rise to justifiable fears that lobbying actually distorts industrial policy.

Industry associations and developing countries

In the context of developing countries Hall (2005) suggests that international organisations, including industry associations, play an important role in facilitating knowledge transfer from the developed north to the developing south; thus contributing to the building of institutional capacities of both government and industry. Kshetri & Dholakia, (2009) argue, that industry associations "are likely to be more effective and efficient institutions" in articulating industry needs, mobilising resources and working with government to develop and implement new regulatory frameworks (Kshetri & Dholakia, 2009: 227).

However, these institutions, they argue, may lack the capacities and perhaps incentives to curtail the interests of MNCs to the detriment of indigenous industries and particular types of indigenous firms (e.g. manufacturing based firms). In other words, it is possible that much of the NIS of a developing country, can, in the pursuit of technology transfer and FDI, become captive to the interests of MNCs (e.g. strong intellectual property laws); these interests supported through the powerful auspices of both internationally based and increasingly domestic industry associations that have significant MNC membership (Papaioannou et al., 2014). Several empirical studies have highlighted the beneficial effects of business associations on industrial development in developing economies (Lucas, 1993; Nadvi and Schmitz, 1994; Mcmillan and Woodruff (1999). Atherey and Chaturvedi (2007) suggests that one common factor emphasised in all these studies is the new nature of competition faced by members of these associations and their desire to overcome common problems through collective action and support from the state. Further, in developing countries inequalities of access to wealth, power and information among different stakeholders provides critical dimension to the relations between the government and industry. In this context the contrasting trajectories of the Indian biotechnology and medical device industry provide interesting case studies to understand the role of industry associations in healthcare industries.

3. Research methodology

This research employs the case study methodology focusing on the Indian biotechnology and medical devices sectors to explore the role of industry associations in growth and development of the industry. India was selected as our empirical research site because of its active involvement in health innovation and its pluralist context that includes different stakeholder competing to further own interests (Athreye and Chaturvedi, 2007). India also has a well-established knowledge-driven health industry (Abuduxike and Aljunid, 2012), and emerged as one of the world's largest suppliers of vital medicines and vaccines' (Kale, 2012). The active involvement of India in shaping global debates on regulatory policies, plural and chaotic policymaking process allowing inputs from NIS actors such as health industry associations provides an appropriate background to this study. The choice of two sectors for study was driven by three factors: contrasting growth and technological capability trajectories shown by India biotechnology and medical device sector, diversity of products and technologies covered by these two sectors, and nature of associations representing these two sectors.

Contrasting growth and technological capability trajectories

India is counted among the top 12 countries in terms of numbers of biotechnology companies and as the lead producer of affordable vaccines globally. In 2013 the Indian biotechnology industry recorded revenue of US \$ 400 mn and registered a 15% growth rate (Biospectrum, 2013) (fig 1), whilst the Indian medical device industry has struggled to show a comparable growth and technological capabilities.

(Fig 1 here)

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). However this industry is not well documented and estimates of its size vary significantly across different sources. There are about 14,000 medical devices marketed in India divided amongst key segments of instruments and appliances used in ophthalmic, dental, orthopaedic and for diagnostic purposes. Over the years the country has become increasingly dependent on imports from countries like the US, Japan, the UK, France, Finland and Germany. This dependence has roots in the industrial and economic policies adopted by the Indian government. Most imported medical devices such as cancer diagnostic, medical imaging, ultrasonic scanning, plastic surgery equipment and polymerase chain reaction (PCR) technologies contain high technological intensity and

earn high gross margins. Commenting on the state of the Indian medical device industry, Kamath (2010) points out 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”

In 2012, Indian imports stood at 1.14% of global import of medical devices while the Indian export share constituted at less than 0.5% of total global exports (Datta et al., 2013). USA is the leading supplier to India with more than 28% products valued \$400 mn coming to India in 2008. The Indian total trade (imports plus exports) in medical devices has steadily risen from 2005 to reach US\$ 2.1 billion in 2010 (WHO, 2012). Fig 2 shows that imports of healthcare products into India grew tenfold in the 1990s and increased by a CAGR of 12.5% from 2000-2010 (Datta, et al., 2013). According to Dutta et al., (2013) in 2010 there were around 356 medical device-manufacturing units accounting for only 0.19% share of the total Indian manufacturing industry. However, increasing imports shows that in most segments, Indian firms are still struggling either to develop devices suitable for local use or find acceptance for their products in the Indian market.

(Fig 2 here)

Diversity of products and technology

Unlike pharmaceutical industry, both medical devices and biotechnology industries cover a diverse set of sub sectors with each of those sectors requiring specialised industrial and regulatory policies. For example, biotechnology industry includes diverse areas such as agri-biotechnology, bioinformatics, bio-industrial and bio-services while medical devices covers segments such as diagnostics, orthopaedic and prosthetic devices, diagnostic and imaging apparatus, dental products and other products. The biotechnology sector in India consists of five sub-sectors (see fig 3). Biopharma (vaccines, insulin and diagnostics) dominates the sector with a 64% share of the market, amounting to more than \$2bn annually, followed by bioservices (clinical trials and contract research) with 18%, then agri-biotech (14%), bio-industrial (3%) and bioinformatics (1%).

(Fig 3 here)

The medical device industry consists of diverse sector similar to the biotechnology sector. Fig 4 highlights these segments and shows that diagnostic equipment accounts for the largest portion of the medical device market in India, enjoying an almost 30% annual average growth rate (Deloitte, 2010).

(Fig 4 here)

The Indian healthcare industry associations

Since 1975, various sector specific and umbrella associations have represented the Indian biotechnology industry and its sub-sectors whilst the Indian medical device industry has lacked strong representation till 2009. Table 1 provides details of the organisation representing the Indian biotechnology and medical device industries.

(Table 1 here)

The contrasting growth and technological capability trajectories observed in Indian biotechnology and medical device sectors, the heterogeneous nature of these sectors and the differences in nature of representation provide an interesting context to investigate role and impact the sector specific and umbrella industry associations.

3.1 Methods of data collection

The data collection for this research was carried out in two phases. In first phase a pilot study was conducted focused on the innovative activities in healthcare delivery, revealing systemic interactions between associations, government and other stakeholders in biotechnology and medical device sector. It also identified key informants to be interviewed. Building on the results of pilot study, the extensive desk-based research mainly analysed annual reports/reviews of associations and the fieldwork focused on face-to-face interviews with high-level representatives of health industry associations, umbrella organisations and related stakeholders.

The primary data for the second phase was collected through conducting interviews with stakeholders and associations representing these two sectors in India. Specifically it involved three types of innovation actors: industry specific associations i.e. the Organisation of Pharmaceutical Producers of India (OPPI), the Association of Biotechnology Led Enterprises (ABLE) and the Indian Pharmaceutical Association (IPA); umbrella organisations i.e. the Confederation of Indian Industry (CII) and the Federation of Indian Chambers of Commerce and Industry (FICCI); and finally related stakeholders i.e. the Indian Biotechnology Industry Research Assistance Council (BIRAC), PriceWaterhouse Coopers (PWC), Serum Institute, Glaxo Smith Cline (GSK), Achira Labs, AiMED (Association of Indian Medical Device Industry) and Sree Chitra Research Institutes. In total 30 interviews were conducted with the key respondents in India. The interviews lasted 30 to 90 minutes with a mean duration of 40 minutes were recorded and transcribed. Both the list of documents and the list of interviewees were identified through an initial pilot study of health industry associations that took place in India. Interview questions focused on their context and historical background, their main activities and their function as public actors of development. Empirical data were triangulated with other sources, including government publications, research journal articles, consultancy reports and media releases. These data were analysed in terms of our conceptual framework of innovation systems.

In the case studies below we explore the co-evolution of industry associations and sectors through documenting histories of their formation and tracking key events that shape the development of these sectors. We examine how firms organised themselves to influence policy processes, and provide an account for different degrees of influence they have been able to exercise. Examination of the historical context of policy making helps identifying patterns of change that earlier policies have either induced or sustained. It aids in capturing the contribution of distinct interest groups that represent various levels of historical and existing power, all working through an incremental and adaptive process. As a result this approach helps in understanding what role if any industry associations played in the contrasting development of biotechnology and medical device sectors in India. As such, the extent to which industry associations facilitated industrial policy was determined on the basis of three criteria: regular systemic interactions of health industry associations with public and private actors (e. g. the state and governments, other associations, etc) focused on regulatory and industry policy initiatives; specific broker activities of health industry associations targeted at creating financial incentives for its members; development of platforms of knowledge diffusion and industry promotion, including conferences, workshops (Papaioannou et al., 2015). Using these three criteria, we excluded evidence, which could not count as systemic and/or interactive enough to ensure consistency with our innovation systems framework.

4. The changing economic and political context in India: From anti-business to pro-business

The Indian economical and political context provides an interesting background to study the role of industry associations in facilitating the development of healthcare industries. India's transformation from a controlled license raj anti-business economy to a liberalised pro-business economy provides a significant twist to the role of industry associations. This change in economic and political environment transformed the power dynamic among different stakeholders shifting policy context towards less coherence. Drawing upon the liberal traditions of pluralism the pre-independence era witnessed the emergence of the multiple industry organisations (Kotchaneak, 1995-1996). The division among Indian business communities based on caste, region and family along with emphasis on public sector development and different priorities of foreign and domestic firms led to emergence of number of umbrella and sector specific organisations representing business and industry in India. The three most prominent associations representing the private sector in India i.e. the Federation of Indian Chambers of Commerce and Industry (FICCI), the Associated Chambers of Commerce and Industry (ASSOCHAM) and the Confederation of Indian Industry (CII) have origins in the pre-independence period. These organisations are still very active in influencing policy environment but differ considerably in age, size, number of interests represented and resources (see Table 2).

(Table 2 here)

Pre-liberalisation period: Era of planned economy

Post –independence in 1947 the Indian government adopted the protectionist policies guided by the ideas of import substitution and inspired by Marxist – socialist beliefs of redistribution and equity. This led to stronger protection of domestic companies, nationalisation of key industries and investment in the science and engineering institutes. In this period the Indian policy environment was dominated by the strong government intervention with significant beliefs in capability of the public sector and limited trust in domestic firms and their industry associations. This 'pro-science and anti-market' Nehruvian vision shaped the Indian economic and industrial policies immediately in the post-independence India (Timberg, 2004). During this period the industry associations in India mainly acted as a supplicant in their dealings with government and was largely reactive than proactive in setting policy agendas (Kochaneak, 1995-1996).

In the era of pre-liberalisation, the interests of pharmaceutical industry were represented by two organisations formed in the 1960s. The Indian Drug Manufacturers' Association (IDMA) was established in Mumbai in 1961 to protect the interests of domestic pharmaceutical manufactures. A key objective for IDMA was to make India self-sufficient in terms of production of drugs and pharmaceuticals. Thus, since its establishment, this association has included only Indian companies of various sizes i.e. large, medium and small companies. In the 1960s MNCs still dominated the Indian market. Domestic companies were just starting work on formulations from imported bulk drugs (Majumdar, 2004). It was the India Patents Act 1970 that enabled members of IDMA to grow their manufacturing of generics and supply the Indian market with affordable essential medicines. Subsequently, the power of MNCs declined to some extent. The interests of MNCs began to be represented in 1965 by Organisation of Pharmaceutical Producers of India (OPPI). OPPI, from the very beginning, considered the tightening of IPRs to be a major incentive for producing innovative drugs and therapies.

In the 1970s, the gradual shift in the attitudes of government and political parties towards the domestic industries led to close relationship between the influential industry houses and policy makers. With the arrival of Rajiv Gandhi in the 1980s climate really began to change in favour of a more pro-business

agenda and that followed by change in the role of industry associations. Kochanek (1995-1996) suggests that during the 1980s the FICCI and the ASSOCHAM associations reorganised and increasingly became mirror images of each other (with differing regional base) but with strong support to protective policies. These organisations represented the older business houses that benefited during the import substitution era and quite wary of increased competition as result of external opening. By contrast, the CII represented emerging technology, export - oriented businesses, more "modern" industries that favoured a more open, competitive economy and a stronger integration with global economy (Kohli, 2006). Different positions taken by these organisations signalled a clear split in the political and policy preferences. Kohli (2006) points out that in contrast to favourable positions taken by CII, FICCI and ASSOCHAM, argued throughout the 1980s for the internal deregulation and "going slow" on the external front. However, this resulted in the FICCI and the ASSOCHAM slowly losing ground to the newly constituted CII in terms of political and policy influence. Sinha (2005) informs that government needed support from industry for liberalisation of the economy and found an ally in the CII. The international activities and policy positions of the industries represented by CII were more in accordance with economic reform planned by the government. In 1985 Rajiv Gandhi, the prime minister, invited policy inputs from the CII as he viewed the FICCI as 'protectionist, weak, fractionalised and an organisation with vested interests in the continuation of the regulatory system rather than its withdrawal' (Sinha 2005:10). As one interview respondent confirmed:

"I think CII was behind reform process from the early 1990s and that is very much credit to the CII, although it wasn't true of other industry organisations. In case of CII it was the combination of membership and quality of the secretariat ... CII represented progressive face of the industry and I regret to say that FICCI ... represented regressive face of the industry" (interview extract: 3)"

Both government and the industry associations, specifically CII, took steps to work in tandem to achieve mutually beneficial objectives. This was the beginning of 'pro-business policies' (Kohli 2006; Timberg 2004) – an informal contract between the firm and state. Ghose (2010) refers to this transformation as 'a shift in how the state and the firm could collude and share a common goal, forged on meshing framings of risk based on an explicitly crafted space for the firm and the state to collude, though mostly behind closed doors'. He quotes the chairman of FICCI stating their ambition for "public-private partnerships" forged on the belief that industry and the private sector should both "be part of the decision making".

Commenting on the policy making process in this era, Kohli (2006) points out the major policy changes are 'pushed forward by a narrow coalition, and element of 'stealth' rather than elaborate democratic process. As the regional head of one of the apex organisation comments,

"I think the way in which policy reform happens in India either you have different currents and different people within the policy framework, whether it is the politician themselves or certainly a bureaucrat who is behind a particular reform or proposal. So you have those going along at the same time and at some point of time things come together and a particular policy after being stalled for long time, it moves and happens. It is difficult to say why it happens"

In fact Cali and Sen (2011) argued that along with CII, the export oriented sectors of the Indian industry, MNCs and the Indian government entered into a 'growth coalition', aimed at enhancing economic growth through increasing the rate of investment in technological innovation and the productivity of investment. However, the advent of economic liberalisation and the integration of lobbying into the political process of policy making opened up a space that had hitherto not existed led to the transformation in the some part of the Indian policy making process (Athreya and Chaturvedi, 2007).

The stage was set for a lobby friendly environment and the collusion between the state and firms created a fertile environment for industry friendly policy formulation in the early days of economic reforms, and, up to a point, firms were quite content with the situation. By the early 1990s, at the height of the battle between FICCI, ASSOCHAM and CII however, the entire political, economic and business environment within which Indian business associations had began to change drastically.

This informal contract between the firm and the state expanded exponentially after the economic liberalisation policies adopted by the Indian government in 1991.

Post-liberalisation: Pro-business

The balance of payment crisis in 1990 and pro-liberalisation political leadership ushered in the economic liberalisation and changed the trajectory of India's trade policy. This involved a reduction of import controls, removal of the 'license – raj', devaluation of the rupee and the opening of capital markets. This period marked by increasing role of industry associations in shaping the economic and trade policy in the interests of their members. The integration of the Indian economy with the global economy emerged as the contentious issue among different industry associations. According to Kochanek (1995-1996:167) the CII had developed such close ties with Indian bureaucracy that it came to be dubbed as the "junior partner" of the government; so much so that the 1993-94 budget came to be called the "Tarun Das" budget, referring to Tarun Das, the director of CII. Kohli (2004) argues that business lobbying by ASSOCHAM and FICCI managed to limit the speed and scope of the opening and integration. These organisations took positions that import tariffs should be reduced gradually and FDI should be limited, prescribing a more selective integration with the global economy. Kohli (2006) contends that over the next decade the active role of industry associations in setting policy agendas became nearly institutionalised with senior government policy official inviting the private sector "to be part of the decision-making" (Indian Express, 2004). According to Newel (2003:18) senior figures within the CII suggests that 'in 99 percent of cases, no new policy is evolved without consulting us'.

The economic liberalisation and opening up for foreign capital brought more scrutiny from domestic and international stakeholders. It further led to the increase engagement with international institutions, civil society actors and judicial activism in the policy-making decisions. In this emerging economic and political environment the actual political process surrounding policy making started getting more complex with different stakeholders with unequal access to power exerting significant pressure on the policy makers. This became prominently evident in the healthcare sector with various policy decisions getting engrossed in the crossfire of different stakeholders. The complicated political process of repealing the 1970 Act and transitioning to the full implementation of the TRIPS requirements is illustrative of government-industry relations during times of extreme regulatory uncertainty.

Lobbying by industry associations has been credited for acceptance of TRIPS as part the WTO agreement by the Indian government (Ramanna, 1999). During the WTO negotiations it was quite clear that India was one of the strongest opponents of the TRIPS agreement. However, in 1989 India made a surprise move and gave up its opposition to TRIPS. Ramanna (1999) credits some private firms and domestic industry associations for influencing government views on change of position at the WTO. The Indian Pharmaceutical Alliance (IPA) formed in 1992 by leading innovative Indian firms as a business association to create, inform and influence government negotiations on the TRIPS agreement. The two leading industry associations, IPA and OPPI, heavily advocated India's adoption of the TRIPS requirements, with these organisations pushing the notion that adhering to these requirements would create an environment conducive to increased investment in R&D, rigorous and safe clinical trials and more effective collaboration between Indian and MNCs. In tune with this, the umbrella organisations such as CII, FICCI and ASSOCHAM began to advocate the need for greater patent protection and started supporting the bill to amend patent laws in conformity with the TRIPS agreement.

Yet, with the emergence of vocal civil society organisations and judiciary activism, all these began to change. Specifically in areas of healthcare and agri-biotech the civil society framings and judicial activism began to encroach on areas of governance and policy making, the industry organisations began to react furthering complicating the policy making the process. This is best exemplified in the framing of clinical trials regulations. In 2009 serious issues were identified in some clinical trials conducted by MNCs in collaboration with the Indian Council of Medical Research. These trials were abandoned in 2010 after the death of seven participants and questions were raised in the parliament. Based on this incident in 2012 an Indian NGO filed public interest litigation in the Indian Supreme Court citing strong mistakes in the process of conducting the trials and asking for stronger regulatory framework. Taking cognisance of the issues in 2013, the supreme court revoked the capacity of the Drugs Controller General of India (DCGI) to approve clinical trials after finding severe irregularities in some of the clinical trials approved. The government responded by amending the Drugs and Cosmetics Act to bring in the tighter regulations for the conduct of clinical trials that included three-tier approval process. This resulted in drastic reduction of clinical trial approvals in India. For first six months not a single approval was given, but in July and August 2013, the health ministry passed 162 trials, prompting the Supreme Court in response to the NGO PIL to question rationale for approvals. Mahalingam (2014) found that the court suspended 157 trials when the ministry clarified that only five trials had been put through the three-tier process, asking them to be re-evaluated under the new process. This prompted many pharmaceutical companies and international sponsors to pull out their trials from India affecting industry as well as patients. In this environment various umbrella and sector specific industry associations are working with the government to frame robust clinical trial guidelines that can favour patients as well as interests of their members. The emerging new power dynamic has altered the lobbying role played by industry associations and led the emergence of 'partners in development' position (Papaioannou et al 2015).

Overall, the introduction of economic liberalisation, and the emergence of influential civil society organisations and judicial activism – in parallel with the involvement of international institutions – have given rise to a new form of government-industry interaction. This transformation in the Indian business environment provides an interesting background to understand the role and significance of industry associations in the development of biotechnology and medical device industries.

5. Evolution of the Indian biotechnology industry and role of industry association

The Indian biotechnology industry has evolved through three different phases; initiation phase (1975-85), development phase (1985-95) and growth phase (post 1995). Fig 5 maps the key points of these phases. Throughout this process umbrella and sector specific industry associations have been involved in the design and implementation of industrial and regulatory frameworks that are intended to satisfy the commercial potential of the industry as well as protect risks associated with its development.

(Fig 5 here)

In the late 1970s the Indian government identified biotechnology as a tool to advance growth of agriculture and healthcare sectors and started investing in the development of the sector. India's Sixth Five Year Plan (1980-85) was the first policy document to cover Biotechnology development (Chaturvedi, 2005). In 1982 the government set up an apex official agency, the National Technology Board (NBTB) to lead biotechnology development and a number of initiatives were launched in the 6th (1981-1985) and 7th (1986-1990) five year plans. In 1986 NBTB was dissolved and the Department of Biotechnology (DBT) was established as a nodal agency that could coordinate development of different

competencies in a variety of scientific disciplines (Ramani, 2001). In 1978 Kiran Muzumdar Shaw established Biocon, a biotech firm to manufacture and export enzymes to the US and Europe. It was one of the first and few biotech firms in India and in 1990 the company shifted focus to biopharmaceuticals. The commercial success of Biocon, Shaw's political contacts and her influential role in setting policies led the Economist (Scoones, 2002) dubbed her as the "Queen of biotechnology" in India. In the 1980s the CII and Kiran Muzumdar-Shaw played a key agenda-setting role in influencing the tone for the debate on reforms to the system of biotechnology regulation in India.

CII was first to pick up the cause of the biotechnology industry. Under the leadership of Kiran Muzumdar Shaw the CII established the core group focused on the biotechnology to provide inputs to the technology and regulatory policy. She heads CII National Committee on the Biotechnology and that provides CII highest levels of access with government departments such as DBT. Newell (2003) points out that CII was represented on all 25 committees within MoEF (Ministry of Environment and Forest) including those dealing with the BioSafety Protocol and Biodiversity issues, as well as sitting on RCGM (Research Committee on Genetic Manipulation). CII also made key inputs into policy process through the publications of industry reports such as the White Paper on biotechnology regulation and these proved useful in informing the government missing links in regulatory infrastructure. For example, accepting recommendation from the CII's White Paper, the DBT proposed a single window application-processing cell as part of a new regulatory system for the domestic biotechnology sector (Chaturvedi, 2003). In this period CII was careful not to alienate government officials, but rather bring them in to their discussions about changes in the regulatory system. Workshops were organised to build bridges and allow for exchange of concerns.

CII established working relation with international industry bodies such as BIO (Biotechnology Industry Organisation) and the Global Industry Coalitions along with counter-parts in South Africa and Europe. These relationships provided CII access to key information, created ties with MNCs and established a strong footprint in the international policy debates. For example, CII, the US-India Business Council and BIO of the US signed a memorandum of understanding covering information sharing on trade and investment opportunities in the biotech sector, facilitation of "one-to-one" interaction between business and government in the US and India and the establishment of a working group to facilitate trade opportunities (Scoones, 2002). CII followed up with similar exercise in India by setting up the Biotechnology India Alliance, an association set up to facilitate development of the biotech sector in India. Through these various initiatives CII lobbied with the government to get tax breaks for investment in research and development, lowering duties, creating appropriate infrastructure and demanding regulatory commission. CII was far more active and aggressive in promoting the biotechnology industry to serve as a 'single window mechanism' for biotechnology policy and regulation' compared to FICCI and Assocham. The issue of 'single window mechanism' brought CII and AIBA, first biotechnology dedicated industry association in India together and created a stronger voice for the industry. As a CII official noted:

'We are trying to sell India as a biotech location. But government needs to do more. It's the bureaucratic process that's important. It is an ad hoc system, with lack of clarity and delays. We need an industry friendly single agency with all the experts in one place'.
(Newell, 2003: 13)

Post 1994: AIBA and lobbying for the biotechnology industry

All India Biotech Association (AIBA) came up in 1994 and was a spin-off from the Pesticide Association of India (PAI). AIBA's long-term vision was to emerge as a 'strong and vibrant organisation to serve biotechnology in India comparable to similar bodies already existing in various European countries, Japan and USA' and 'represent the interests of all those engaged in the various aspects of

biotechnology' (AIBA, 2000). It had three categories of membership of private firms, academics and government research institutions and represented these stakeholders in a more promotional capacity (Newel, 2003). To augment the development of biotechnology sector in India, AIBA focused on the three critical areas of IPR regulation, biosafety regulation and import and export excise duty. Table 3 details the different promotion and policy initiatives lobbied for by AIBA.

(Table 3 here)

The major influence of AIBA on government policy came through its representation on the Development Task Force set up by the DBT and 'cumbersome' regulatory processes emerged as major area of discussion between government and industry association. In 2000 AIBA produced an influential report, which was critical of the government, argued for simplification and rationalisation in the number of authorities required to give product approval. In 2003 AIBA was instrumental in organising the highly successful international level 'Biotech Invest, 2003' conference that resulted in significant collaboration activity for domestic and foreign firms (Business Line, 2003). In this period AIBA's membership increased from 140 in 1995 to 260 in 2005. Building on this in 2005 AIBA got involved in setting up of 'Federation of Asian Biotechnology Association' with Asian countries as members. However, post 2005 the inability of AIBA to satisfy the interests of different firms operating in the biotechnology sub-sectors led to membership shrinkage and suspension of their flagship publication, AIBA News Letter (Athrey and Chaturvedi, 2000). Several of its members left the AIBA and started industry organisations to suit requirements of their particular sector. The biopharmaceutical companies that left AIBA were joined by a group coming out of Confederation of Indian Industries (CII) and the Confederation of Indian Food Trade and Industry (CIFTI) of the Federation of Indian Chambers of Commerce and Industry (FICCI) to establish the Association of Biotechnology-Led Enterprises (ABLE).

Post 2003: ABLE- Moving towards strategic partnership

Association of Biotechnology Led Enterprises - ABLE was launched in February 2003, after industry leaders felt a need to form a separate association, as special committees of CII or FICCI would not get them what they were looking for (in policy terms) from the government, precipitated by lack of representation by AIBA. In the beginning period ABLE received leadership from Kiran Muzumdar Shaw and that helped ABLE to gain credibility and access. She comments,

I'm a multi-faceted person because I sit on many industry boards, right, I sit on ABLE, I'm a part of CII, I was on the Prime Minister's Trade and Commerce Advisory panel, and of course because of my various interactions I know ministers pretty well.

(interview extract)

As a result the membership in ABLE grew very fast. In 2003, the membership was 28, increased to 165 in 2006 and by 2015 it has over 580 members from all across India representing all verticals of the sector like agri-biotech, bio-pharma, industrial biotech, bioinformatics, investment banks and Venture Capital firms, leading research and academic institutes and law firms and equipment suppliers.

Similar to AIBA the primary focus of ABLE is to accelerate the pace of growth of the Biotechnology sector in India through various promotional initiatives, coordination activities and entrepreneurship activities but unlike AIBA a significant number of ABLE initiatives were supported and funded by DBT (Table 4).

(Table 4 here)

ABLE is providing a platform for domestic and overseas companies to explore collaboration and partnerships and showcasing the strengths of the Indian biotech sector (Table 4). A senior official suggests,

we're looking at partnerships, for instance we have a very strong linkage with bio in the US. We are now forging a big alliance with Japan, we have a big alliance with Korea, with Australia, so we have these four very strong partners, and one more is with the UK. So we have these very, very strong partnerships, with people and these organisations, and those also help us to basically bring companies together from these countries and see if there are any synergistic opportunities. (interview extract)

ABLE has opened an office in the US and represents the Indian biotechnology industry at the international conferences to attract attention of investors and facilitate entry of Indian firms overseas markets.

Over the years, ABLE has developed a strong relationship with 'BioSpectrum' magazine and adopted it as the voice of the organisation and biotech industry. Post 2000 Bio-Spectrum annually publishes strong research teams and experts who collect data about their members' activities, including R&D and commercialisation of new products. In addition, ABLE works with consultancy firms to provide data and analyses of trends in biotechnology sectors and emerging opportunities and challenges. A senior functionary revealed,

"...we have published a booklet which we are going to different ministries with ... trying to say to them [to] look at it from this level or that level ... Also we are trying to make a 100 days programme for the government in aid of biotechnology, pharma, healthcare, life science, innovation ... we will apply to government soon and say this is our 100 days programme, this is our wish list and what can you do? Then they may call a meeting and that is the interaction that goes on" (interview extract)

This collection of data and emerging trends and relationship with 'BioSpectrum' has helped ABLE emerge as a credible voice of the Indian biotechnology industry and provided access to engage with policy makers on needs of the industry. On this basis, ABLE has created a strong partnership with the DBT and contributed to development of financial schemes to encourage entrepreneurship and investment in the sector. For example, ABLE annual initiatives like North Eastern Entrepreneurship Development Programme and Bio invest conference are funded by the DBT. ABLE worked with the DBT on need for the development fund for biotech entrepreneur and in 2011 DBT launched Biotechnology Industry Research Assistance Council (BIRAC) focussed on providing funding and mandate of strengthening the innovation research capacities of the biotech entrepreneur and providing an enabling ecosystem. A senior board member at ABLE suggests,

We have a strong base in Delhi and we interact. . . we work very closely with the Department of Biotechnology, the Department of Biotechnology is very informed about all the challenges and they also lobby for us. They are a part of the government but they lobby for us with the Commerce Ministry, the Health Ministry, and they are very cognizant of all the issues that we are addressing (interview extract)

The close working collaborative relationship between ABLE and DBT indicates the formation of strategic partnership between industry association and policy making. However, in case of clinical trials regulations the intervention of the Supreme Court and active involvement of civil society organisations has brought this relationship under more scrutiny. ABLE has representation in Roy Choudhari

committee set up to frame clinical trial regulations and now working with DBT to streamlining the clinical trial regulations and bringing them in line with the international standards.

From the 1980s Indian biotechnology industry grew in strength based on the strong communication between industry associations and the policy makers. This led to the provision of financial support from the Indian government, development of research infrastructure, and promotion of local entrepreneurship, has facilitated the development of a strong national biotechnology industry.

5.2 Evolution of the Indian medical device industry and role of industry association

In contrast to biotechnology, the Indian medical device industry is highly fragmented with approximately 360 domestic medical device manufacturers covering different segments. Indian firms are strong players in the low-tech medical device market for furniture and other instruments, which do not come in direct use in treatment. These essential ancillary instruments for the hospital industry constitute a substantial part of medical device production in India. However, just a few Indian firms are engaged in the production and development of critical care and surgical devices (Datta et al. 2013). By contrast to the Indian biotechnology industries, the evolution of the Indian medical sector is shaped by key events, but with little government and industry organisation involvement till 2005 (Fig 6 here).

(Fig 6 here)

The current status of the industry is captured by the following introductory paragraph in a vision document CII published in 2015,

“Little is known about the medical technology industry in India today. Even estimates of market size vary significantly. Pricing is not transparent to the consumer leading to a general perception is that it is dominated by large imports from foreign multinationals that are self seeking and profit making. Little has been done to address this perception”

This quote clearly reveals that unlike the biotechnology sector, the medical device sector has suffered from lack of promotional, knowledge dissemination, policy related and entrepreneurship activities from umbrella and sector specific industry associations. This lack of attention from the industry association has detrimental effect on growth of the industry and contributed to adoption of misguided regulatory and industrial policies from the Indian government.

Post independent: Invisible Medical device sector

In the post independent India, the prevailing rates of tariff on medical devices were around 40 to 60 per cent until 1990, though ‘life saving’ medical devices could be imported duty free (Mahal et al., 2009). During this period a majority of the Indian population had very limited access to medical devices and market size was US\$ 280 million (Ramani and Rameseshan, 1989). The first major achievement for the Indian medical device industry was the indigenous development of the Jaipur foot; a leg and foot prosthetic made of locally available soft materials, by craftsman Ram Charan Sharma and surgeon Pramod Sethi in 1968. The co-inventors then joined the Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS) to develop a business model that leveraged approximately 60% of total funding from donations, 30% from government support with the remaining 10% from earned income. In 1975 BMVSS started offering free prosthesis in India under BMVSS. This success spurred the establishment of the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMSCT) in 1976. This hospital was established with the aid of the Royal Family of Travancore and had a biomedical

technology wing dedicated to the development of medical devices. This proved significant in laying the groundwork for future development of the Indian medical device industry.

Post 1990: Economic liberalisation and MNC domination in local markets

After economic liberalisation in the 1990s the increasing size of the healthcare market gave a boost to domestic firms and also led to increased imports. The Indian government significantly reduced import tariffs on medical devices to the range of 15 to 30 per cent and de-licensed imports. Growing between 15 and 20% a year in 1990s, India's market for medical devices reached \$680 million in 1995 (Kader and Priestly, 1997). In 1995 more than 90 local firms were prominent with 22 dominating production, joint ventures and collaboration with overseas firms. There was a significant increase in imports. The US exports to India reached US \$ 57 million, a 19% increase from 1994 constituting a 40% market share (Kader and Priestley, 1997). However this increased import did not resolve issues of affordability and appropriateness.

During this period there was total absence of representation from the industry organisation. MNCs were dominating the domestic market in high-tech and 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. The small size of domestic industry, diverse nature of products and absence of strong industrial leadership resulted in neglect of the medical device sectors from any umbrella or apex industry associations. A CEO of diagnostic company highlights this neglect,

If you build enough revenues, if you build enough noise, you can lobby better. Biggest Indian medical device companies have low revenues, how much can you really lobby.

(interview extract)

This absence of communication between industry and policy makers led to the development of Indian industrial policies that indirectly rewarded imports rather than manufacturing firms operating in India. For example, the Indian government provides import duty exemption for equipment and technologies that are not available in the India but charges custom duty for imported raw materials required to manufacture those products locally. The absence of industry association was strongly felt in regulatory neglect of the industry by the Indian government. Majority of the devices were sold without any monitoring by a regulatory authority and this lack of oversight opened the door for low quality devices to enter the market and weakened Indian manufacturers' capacity to export to international standards. The issues of regulation came to forefront in 2005. The state run hospital in Mumbai used an unapproved drug eluting stent on patients and 60 patients were harmed. Taking cognisance of this issue, the High Court ordered the Indian government to frame standards for medical devices marketed in India. The Indian government then brought 10 medical devices under the jurisdiction of the Drugs and Cosmetics Act, 1940. However it became evident that the regulatory framework and infrastructure designed to govern pharmaceutical and cosmetic products is totally inadequate for governing medical devices due to the difference in products, their action in human body and packaging. This wrong regulation proved turning point in the government-industry linkages in the medical device sector.

Post 2000: CII, AiMed and green shoots of representation

By 2000 the Indian healthcare market was growing at the 15 % CAGR and medical equipment market at 17% per annum. This growth brought focus on the operations of domestic firms and led to formation of Medical Device Equipment division in the umbrella industry associations. For example, CII has formed the National Committee on Healthcare and CII Medical Equipment Division to provide a nodal point of reference for the Industry, providing a forum for dialogue with the customers & government and

formation of appropriate regulatory structure. However, lack of sector specific industry association became apparent in 2005 when the Indian government categorised medical devices as drugs and put them under Drugs and Cosmetic law. There was no sector specific industrial association to educate government on needs of the sector and that resulted in preliminary consultations with few secondary stakeholders. This spurred all the industry associations into action. CII launched 1st Indian Medical Technology Conference in 2007 as a platform for bringing policy makers, domestic firms and MNCs together to promote needs of the Indian industry and discuss the way forward in addressing these challenges. CII have established this as an annual event and brought in Deloitte, a consultancy firm as a knowledge partner. However, the limited representation by the umbrella organisations such as CII and FICCI, their positions on import duties and economic liberalisation led to formation of two sector specific industry organisations focused on diagnostic and medical device industries in 2002 and 2009 respectively. In 2002, around 19 diagnostic manufacturers – both Indian and MNCs – came together to form the Association of Diagnostic Manufacturers of India (ADMI). The main objective of this association is to educate government (state as well as Central) about the difficulties and bottlenecks faced by the diagnostics industry with a view to ensure healthy growth of this industry. ADMI involved some form of knowledge dissemination activities in form of workshop on experts on IPR related issues and GMP manufacturing practice. Further ADMI is pushing for uniform VAT tariff for diagnostics throughout the country as par with that applicable to drugs and medicines. By 2005 similar promotional initiatives were undertaken by other umbrella industry associations (Table 5).

(Table 5 here)

The application of an ineffective regulatory framework and limited representation by umbrella industry association triggered the formation of the Association of Indian Medical Devices (AiMED) as a forum to cover common issues of Indian device manufacturers. Mr V. Agarwal from M/s Surgiwear, a conveyor for AIMED comments,

“the industry needed to create a forum to cover common issues of the stakeholders. So, we all decided to form an umbrella association of Indian Manufacturers Medical Devices covering all types of medical devices where consumables, disposables, equipment or diagnostics. AIMED will provide the larger and more powerful single platform when needed” (AiMED, website)

Similar to ABLE and AIBA, AiMED is covering all segments of Medical Devices, including consumables, disposables, and diagnostic equipment: representing the interest of over 700 Manufacturers of Medical Devices. AiMED aims to emerge as a single point of contact to government on matters of medical device industry, advocacy, information and educational service provide to its members and lobby for funding for funding from the government.

The concerted effort by different industrial organisations forced the Indian government to form the Indian Medical Device Regulatory Review Group in 2009 as a forum for the regulated/unregulated industry, the regulator the conformity assessment bodies, the testing institutions and consumer groups for bringing up these overdue reforms. AiMED, along with other industry associations, made a strong representation on this forum; this led to framing of specific regulations for medical device industries in 2014.

If issues of regulation brought these associations together, then issues of industrial policy led to divisions between the industry associations. The Indian government continued to reduce import duties, eventually to 12.5 per cent by 2004. By 2013 custom duty on medical devices was charged at a uniform rate of 5 per cent with countervailing duty of four per cent and with complete exemption from special additional duty. This led to a sharp increase in both volumes and value of imports (Mahal et al.

(2012). In 2014 the Indian government opened the medical device sector for 100% foreign direct investment as incentive for MNCs to set up manufacturing base in India. CII along with other umbrella association favoured this policy move by the government whereas AiMED took contrasting stand by arguing that this will harm the interests of domestic manufacturers. This divergence of industry voices is providing contrasting inputs to government on the favoured industry options affecting the development of coherent industrial and trade policy in the Indian medical device sector.

6. Analysis and discussion

The cases presented here highlight the 'proactive' role of the industry associations in biotechnology. They have substantially contributed to remarkable success and growth of industrial technological capabilities. In many ways, the contrast between the Indian cases of medical device and biotechnology industries shows detrimental consequences due to absence of industry associations and reveals negative impact of 'reactive' role. Table 6 presents the comparative analysis of different activities undertaken by the industry association in the biotechnology and medical device industries.

(Table 6 here)

6.1 Significance of 'proactive' role

The industry association approach towards biotechnology differed significantly compared to the industry association approach to medical devices. In the case of biotechnology, industry associations purposefully created linkages with international organisations, participated in the international conferences and employed consultancy companies to prepare research-based reports on future of the growth and policy recommendations to achieve this. In some cases these reports inflated the projected growth but that helped associations to gain mind space in the policy makers. These proactive activities and creation of information has helped industry associations in reduction in transaction cost for the government and policy markers. It also allowed industry associations to improve on issues of trust while working with different stakeholders. Highlighting significance of these activities head of umbrella association points out,

Currents are all there and I think industry association's job is to have its data together, its facts together, its argument and persists with those arguments for many years and then some point of time either because right ministers are in placed or some impulse from outside or right minister and right secretary come together and something happen. If you haven't played your part or have right information in place then even though right minister and right secretary is there, nothing will happen. To have played your part and got right ideas there and then they are not moving, then it comes together and then it moves (interview extract).

The absence of industry associations in medical devices and the reactive nature of their activities in post 2000 era have created challenges of trust and restricted their influence in shaping policy initiatives. However CII is following a similar route by involving a consultancy firm as a knowledge partner to create industry policy reports suggesting change to this approach.

6.2 From lobbying to strategic partnerships for innovation

As such, the issue of clinical trials and medical device regulations revealed the changing power dynamic among different stakeholders. These two examples highlight the growing role of civil society organisations and judicial activism in shaping regulatory policies in healthcare segments. In the case of biotechnology industries ABLE established a collaborative relationship with DBT by working on different

social initiatives such as entrepreneurship support, knowledge dissemination and development of biotechnology curriculum in universities. This transformed the role of ABLE from lobbyist to more strategic partners with DBT, helping to facilitate the development of biotech sector. In the case of medical devices, the lack of coherent positions on issues of industrial and trade policy is clearly pushing industry associations to collaborate with government departments and thereby reducing their bargaining power in the emerging new scenarios. That being said, this study builds on more recent literature that point to the importance of building and then presenting broad industry coalitions as a prerequisite for gaining effective access to and exerting influence on the government policy making process. The seeming importance of umbrella organisations, e.g. CII, in this regard is evidence in point. As such, industry associations that have been historically ineffective might gain a more receptive government hearing, albeit indirectly, by joining a broader coalition of industries that share similar views on IP, this under the banner of a large umbrella organisation. Furthermore, it could be argued that engaging government with the backing of a larger more inclusive coalition could prove effective in bridging divisions within government surrounding particular industry issues.

In looking at proactive, biopharmaceutical industry associations such as ABLE, the findings presented here support previous studies that position industry associations as key intermediaries in the NISs of developing and emerging countries. The industry associations studied here all engage in significant knowledge transfer and diffusion activities. On the one hand, they collect and package information from their members concerning their member's needs and then articulate this to government, i.e. transferring considerable industry knowledge to government; in doing so, influencing government policy and regulation. On the other, they facilitate the implementation of that regulation, and also coordinate the push-back against it, by informing their members as to the details and implications of proposed or new regulation and standards. This transfer and then exchange of knowledge, even in cases where there is considerable conflict between government and industry, facilitates institutional capacity building on both sides. Furthermore, the industry associations studied here, to some degree, all engage, in network building, both through the establishment of relations with key members of government, i.e. connecting industry to government, and connecting their members to one another; this can foster collaboration within the industry, both on issues of policy and perhaps between member companies in areas of business and joint R&D. Therefore, despite the long-standing negative connotations ascribed to industry associations, the activities described here and in other work, clearly demonstrate that industry associations facilitate necessary interaction between institutional actors and in doing so, contribute and shape recursive learning and subsequent innovation processes.

7. Conclusions

This paper focused on the neglected role of industry associations in developing countries as key intermediaries in innovation systems. These intermediaries through evolutionary processes of conflict, negotiation and knowledge diffusion facilitate institutional capacity building while shaping regulation and subsequent industry development. Using case study methodology and contrasting growth of biotechnology and medical device industries, this paper analysed the role of industry associations in shaping the development of healthcare sectors in India. The findings from this paper highlight that in the case of biotechnology, sector specific industry organisations and especially ABLE contributed to growth of the industry by being 'proactive' about the infrastructural and regulatory policy needs of the industry and communicating that to government with coherent voice. The case of Indian medical device sector provides a counterexample, highlighting consequences of lack of industry association on the growth and development of technological capabilities.

In healthcare industries, the complexity of the knowledge base, diversity of sectors and evolutionary

dynamic of industrial development result in a gap between institutional mechanisms required for supporting the growth and capability development and existing institutions. Policy makers struggled to grasp these changes and required inputs from various sources to plug these gaps. In the case of Indian biotechnology industry associations assisted in bridging this gap by playing key role in shaping IPR legislation and regulatory frameworks. The Indian government lacked the capacity and understanding of regulatory framework required to govern the emerging new technology. Industry associations emerged as an important source of ideas for regulations and in filling the vacuums of no regulations. The Indian government interacted with international industry associations, hired consultants to conduct sector studies and engaged with advanced country regulatory institutions to come up with new insights to resolve local challenges. In the case of medical devices the absence of industry associations resulted in the filling up of those gaps with wrong regulations and inappropriate trade and industrial policies.

The findings also reveal that regulations in the healthcare sectors of developing countries continues to be under scrutiny creating challenges for government to deliver appropriate regulations protecting health but also incentivising industry. In India the case of clinical trial and medical device regulations clearly demonstrate that the emerging active role of civil society organisations and judicial activism have led to change in power dynamic among different stakeholders. This changing dynamic has forced industry associations to adjust their role in the biotechnology industry from being lobbyist to being more strategic partners working with government departments to achieve social objectives. In the medical device sector the lack of coherent voice among the different industry associations have restricted creation of strategic partnerships and led of emergence of diverse agendas.

To conclude, it is evident from this research that development of the Indian bio-medical industry in a way that both builds its globally competitive innovation capacities while effectively addressing its local healthcare needs will require a greater trust and transparency and more complimentary relations between industry and government. Furthermore, policy creation and implementation is complex due to the fact that it is inherently political, and therefore controversial. To achieve industrial development among the conflicting perspectives and interests of various institutions and organisations, industry associations will have to embrace a partnering approach by aligning interests of their members groups with wider healthcare objectives of the country.

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Tables and figures

Table 1 Industry associations representing the Indian biotechnology and medical device industry

Sector	Sector specific	Umbrella industry association
Biotechnology	All India Biotech Association (AIBA, 1994), Association of Biotechnology-Led Enterprises (ABLE, 2003), All India Crop Biotechnology Association (AICBA, 2003), Seed Association of India (SAI)	Federation of Indian Chambers of Commerce and Industry (FICCI), Confederation of Indian Industries (CII), ASSOCHAM (Associated Chambers of Commerce and Industry of India)
Medical devices	Association of Medical Devices Industry (AMED, 2007), Association of Diagnostics Manufacturers of India (ADMI) (2002)	

Table 2 Key characteristics of Indian umbrella/apex industry organisation

No	Name	Year	Nature of members
1	Assocham	1920	The oldest and now represents both large family-owned indigenous business and foreign multinationals
2	FICCI	1927	the largest, most broadly based apex association and tends to represent older, more traditional, indigenous, family-owned business
3	CII	1982 (merger of the Indian Engineering Association which had been created by British entrepreneurs in 1895 and the Engineering Association of India founded by Indian capital in 1942	the newest and richest apex association and tends to represent newer sunrise industries including electronics, software and computer technology.

Table 3 Key activities of AIBA

No	Nature of activity	Year	Description of the activity
1	Knowledge dissemination activities	1997	National Conference on Biopesticides in New Delhi National Conference on Transgenics, Tissue-culture and Floriculture in New Delhi Cosponsoring of Workshop on "Status of Biopesticides in Punjab" at P.A.U., Ludhiana
		1999	National Symposium on HRD requirements of Biotechnology in Agriculture Sector at P.A.U., Ludhiana Organizing Special Scientific talks on "Biotechnology in Pharmaceuticals", "Historical Developments & Future of r-DNA technology & regulatory issues in biotechnology industries in India, Hyderabad National Conference on "Biotechnology in Food Processing" in New Delhi
		2000	Symposium on "Emerging Trends in Biotechnology for the New Millennium
		2001	Colloquium on 'Good Laboratory Practices: Path towards globalization, Hyderabad National Conference on "Biotechnology - the Science an the Business" , New Delhi
		2002	International Conference on Emerging Trends in Biotechnology: Stem Cells - Technology, Potential & Trends, Hyderabad
		2006	Jointly organizing an International Conference on "Biotechnology for Sustainable Agriculture and Agro-Industry, Hyderabad
		2007	Supporting an International Conference on Bio informatics, Hyderabad
		2009	Organizing seminar on emerging trends in Biotechnology, Hyderabad
		2	Promotional activities
2000	Co-Sponsoring of Exhibition and Conference under the name of "Biotechnology India - 2000" at New Delhi		
2003	Biotech Invest-2003: Global Meet on Strategic Alliances & Business Opportunities, Hyderabad Participating and highlighting principal activities of Indian biotechnology Industry in the second Indo - Asean Business meet, New Delhi		
2004	Organizing a major event in biotechnology "BioAsia 2004 - Conference and Business Forum, Hyderabad		
2006	Organizing a major event in Biotechnology "Bio-Asia 2006- Conference and Business Forum" at Hyderabad		
2007	Organizing a major event in Biotechnology " Bio Asia 2007 - The Global Business Form" at Hyderabad Jointly organizing a Bioroad show in New Delhi in association with Korea Bio Venture Association (KOBIOVENO		
2008	Organisation of major event in Biotechnology viz. "Bio Asia 2008: The Global Bio Business Forum" at Hyderabad Organizing an Indo-Australian Networking Meet, New Delhi		
2009	Supporting the international event " Biologics India 2008 Organizing a major event in Biotechnology viz. "BioAsia: The Global Bio Business Forum" at Hyderabad		

3	Entrepreneurship supportive activities	2000	Organizing "Entrepreneurs meet for commercialization of Eco- friendly Technologies of Bio pesticides and Bio fertilizers for Crop Management
4	Regulatory, trade and industry policy related activities	2000	'Single window clearance' regulatory process

Table 4 Activities of ABLE

No	Nature of activity	Year	Description of activity
1	Knowledge dissemination activities	2011	Boot Camp- Intellectual Property 2011 ABLE-Ag conference
		2012	Workshop on Enterprise Building and Innovation by DBT & ABLE, Bangalore and Delhi Seminar on Intellectual Property, Global Practices and Patent Laws De-risking innovation in a developing world, Hyderabad Anti-Cancer workshop in collaboration with DUKE University and OSHL
		2013	Bangalore Nano
		2014	27th International Carbohydrate Symposium, Bangalore World Congress on Stem Cell Research, Cancer Biology and Applied Biotechnology (Biotech-2014) 5th International Conference on Stem Cells and Cancer (ICSCC-2014): Proliferation, Differentiation and Apoptosis
2	Industry promotion activities	2001	Bangalore India Bio 2001
		2005	Promoting Indian Biotech industry in the US
		2006	Project Growth of Bio industry
		2010	Bio International Convention, Washington DC
		2012	Bio International Convention, Boston Bio Tech Expo 2012 11th Bio Technology Exhibition and conference Genepool Role of Agri biotech in enhancing global competitiveness for ABLE-AG, Chandigarh Seminar at Denmark's Medicon Valley event, Mumbai and Hyderabad in collaboration with Invest in Denmark Bio India 2012 co-hosted event with Bio International organisation (US) Hosting Metro Atlanta Chamber (USA) for visit to India
		2013	Genepool BIO KOREA, Kintext India Lab Expo, Hyderabad
2014	Bangalore India BIO Bio Asia 2014, Hyderabad Bio Pharma, Singapore Bio Asia International Conference, Tokyo		
3	Entrepreneurship supportive activities	2009	Organisation of Biotechnology Entrepreneurship Student Teams 2009 event
		2010	North East Entrepreneurship Development Workshop Organisation of Biotechnology Entrepreneurship Student Teams 2010 event
		2011	Organisation of Biotechnology Entrepreneurship Student Teams 2011 event North East Entrepreneurship Development Workshop, Guwahati

			Role of industry- academia linkage in fostering innovation the Biotech ecosystem in Tamil Nadu
		2012	North East Entrepreneurship Development Workshop, Shilong Organisation of Biotechnology Entrepreneurship Student Teams 2012 event, Bangalore in collaboration with DBT ABLE - WBBA signs MoU, industry interaction, New Delhi 3rd North East Life Science Entrepreneurship Workshop, Sikkim completely funded by DBT Northeast Entrepreneurship Development Workshop, Sikkim in collaboration with DBT
		2013	4th North East Life Science Entrepreneurship Workshop completely funded by DBT Biotechnology Entrepreneurship Students Team (BEST) initiated by DBT and organised by ABLE Stimulation Bio Entrepreneur Talk Nascent Entrepreneur Development Programme North East Entrepreneurship Development Workshop
4	Regulatory, trade and industry policy related activities	2003	Lobbying with Ministry of Environment and Forest for Supremacy of RCGM decisions on safety purpose
		2004	Lobbying with Ministry of Environment and Forest for Mashelkar Task force on recombinant products Lobbying with Ministry of health for single window approval process
		2011	High Level Conclave: India's biotech vision 2025, Bangalore
		2013	Lobbying with Roy Choudhari committee for clinical trial regulations
5	Finance support activities	2008	Organisation of BioInvest event
		2009	Organisation of BioInvest event
		2010	Organisation of BioInvest event
		2011	Organisation of BioInvest event
		2012	Lobbying with DBT for setting up BIRAC
		2012	BioInvest, New Delhi
		2014	BioInvest, Mumbai BioInvest in Gujarat, Gandhinagar

Table 5 Industry associations' activities in support of the medical device industry

No	Nature of activity	Year	Description of the activity	Name of the associations
1	Knowledge dissemination activities	2009	Workshop on FDA and CDRH regulations for medical devices National conference on medical devices moving up the value chain Tech awareness meet on quality assurance and radiation safety	FICCI
		2010	National workshop on medical device regulations in India 2nd workshop on UFDA and CDRH regulations for medical devices	
		2014	FICCI - AERB Awareness program on Radiation Safety & Quality Assurance	
2	Industry promotion activities	2008	1st Medical Technology Conference	CII
		2009	2nd Medical Technology Conference	CII
		2010	3rd Medical Technology Conference	CII
		2011	International conference on Medical electronics Launch of FICCI-Deloitte Thought Paper titled "Indian Medical Electronics Industry-Outlook 2020" Launch of FICCI-Frost & Sullivan Report titled "Assessment of Factors determining Accessibility of Medical Devices in India"	FICCI
			4th Medical Technology Conference	CII
		2012	5th Medical Technology Conference	CII
		2013	6th Medical Technology Conference	CII
			Interactive Meeting with UKTI Medical Device Mission Global congress on investment opportunities in medical electronic and devices	FICCI
		2014	7th Medical Technology Conference	CII
Indian Medical device Summit	ASSOCHAM			
3	Regulatory, trade and industrial policy related activities	2009	Roundtable discussion with Minister for Health and Family Welfare	FICCI
			Regulatory reform and initiates the formation of Indian Medical Device Regulatory Review Group Abolishment of exemption from custom duty for 111 items to protect domestic industry	AIMED
		2010	Vision for Medical Electronics a Road for Opportunities and Inclusive Benefits" for Ministry of Health and Welfare	FICCI
		2012	Changes in excise duty specified raw materials used for medical device industry Setting up of separate department for Medical Devices to attract investors	AIMED

		2013	FICCI roundtable on challenges and opportunities in the medical device sector in India	FICCI
		2014	Consultative Meeting of IVD Industry Stakeholders	FICCI

Table 6 Industry association activities in support of biotechnology and medical device industries

No	Nature of activities	Biotechnology industry	Medical device industry
1	Regulatory, industrial and trade policy	<p>An active participation in setting up regulatory governance for health and agri related biotechnology. Association commissioned studies with reputed consultancy and formed strategic partnerships with DBT</p> <p>Engaged with biopsepctrum magazine to map the output of the industry on annual basis and created voice for the industry</p>	<p>No critical inputs to the development of policy from industry associations till 2005.</p> <p>Differences among industry associations harming growth of the sector</p> <p>Lack of trustworthy data on the domestic firms and no mapping of the industry</p>
2	Industry promotion activities	From early period various industry associations made a coherent effort to promote industry. Annual conference, participation in international conference were regular	Sporadic efforts from umbrella industry associations post 2008 but lacked any focused effort
3	Knowledge dissemination activities	Regularly arranged workshops for members on issues of regulation and best practices, assisted in development of biotechnology curriculum programmes	CII, ADMI and AiMED are engaging by arranging workshops for members
4	Entrepreneurship supportive activities	Formed partnerships with government to promote entrepreneurship with events such as Bio-Invest and North Eastern Entrepreneurship conference	Quite nascent and diversity of segments affecting organisation of these initiatives
5	Finance support activities	Lobbied with government and that led to formation of innovation fund in form BIRAC	Lack of coherent position affecting development of any supportive policy
		Proactive approach by industry associations contributed to growth and development of the industry	Reactive approach by the Industry associations proved detrimental to growth and development of the industry

Figures

Fig 1 Growth in the Indian biotechnology industry (ABLE-Biospectrun survey, 2003-2013)

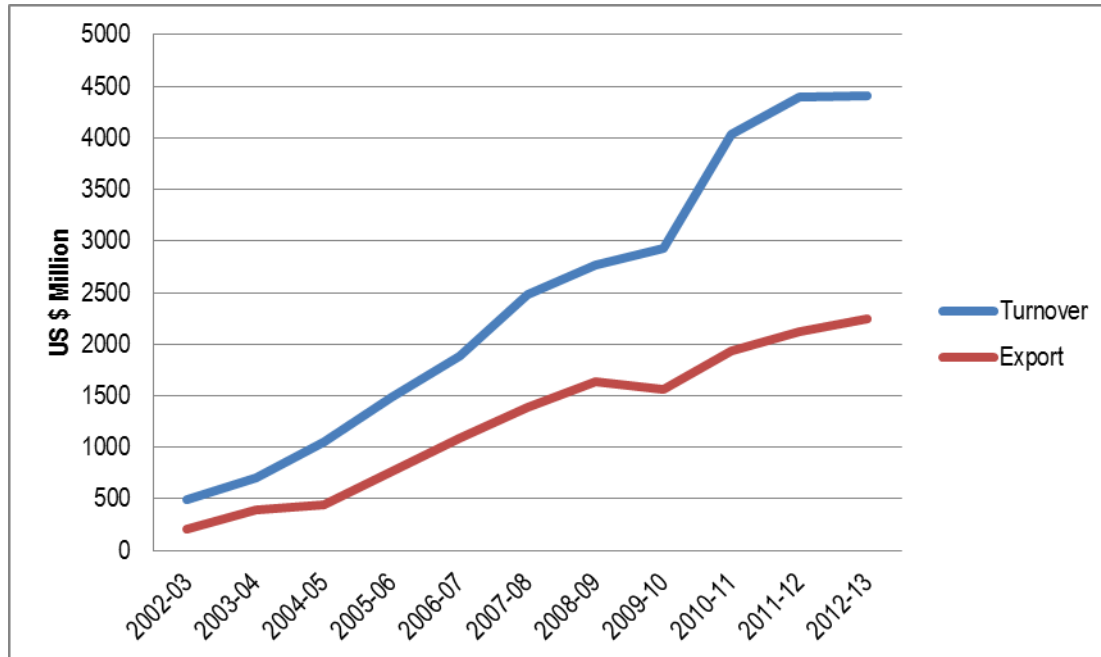


Fig.2 Import growth rate for medical device products (Datta et al., 2013)

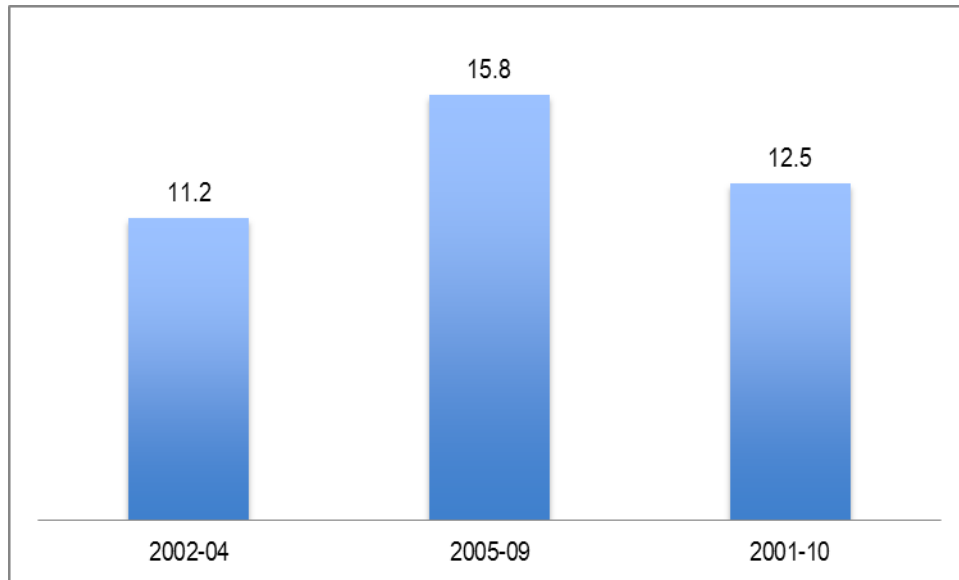


Fig 3 Key segments in the Indian biotech industry

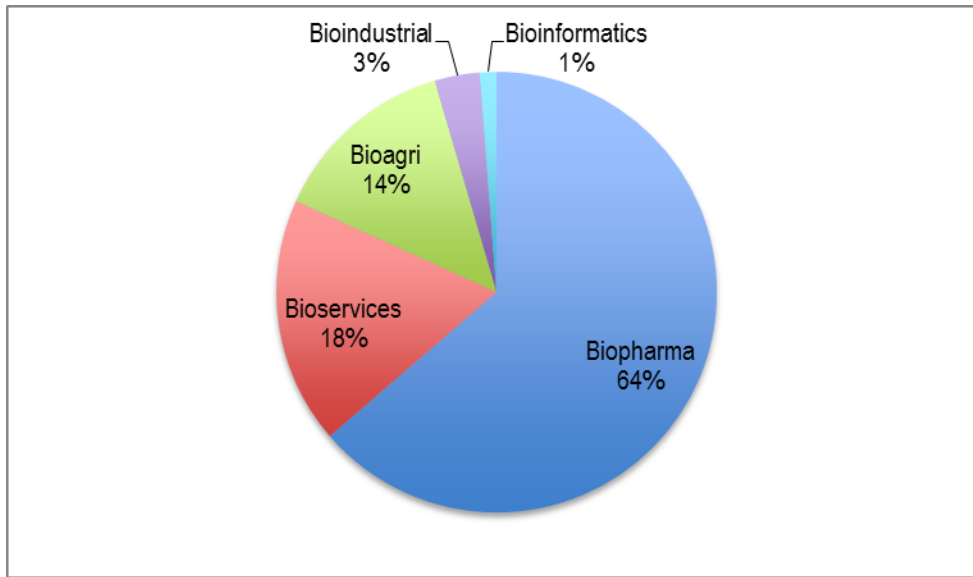


Fig. 4 Market distribution of Indian medical device industry for 2008 (Deloitte, 2010)

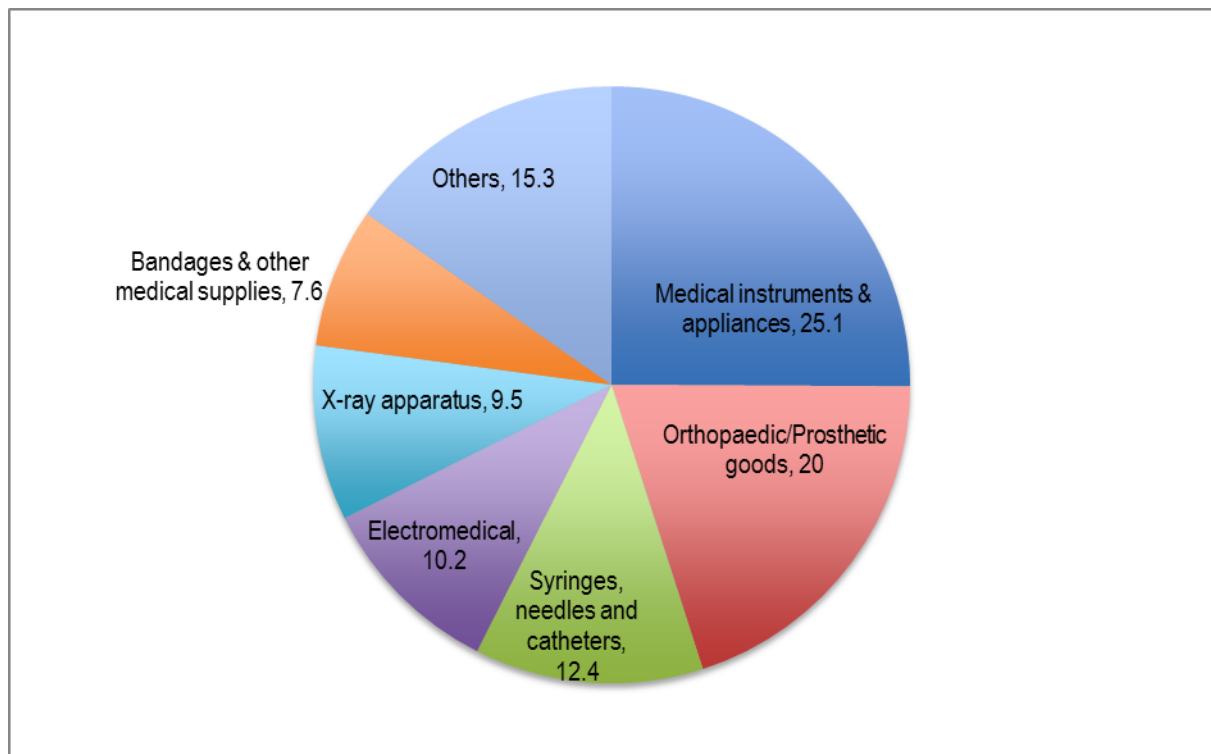


Fig. 5 Evolution of the Indian biotechnology industry and role of industry associations

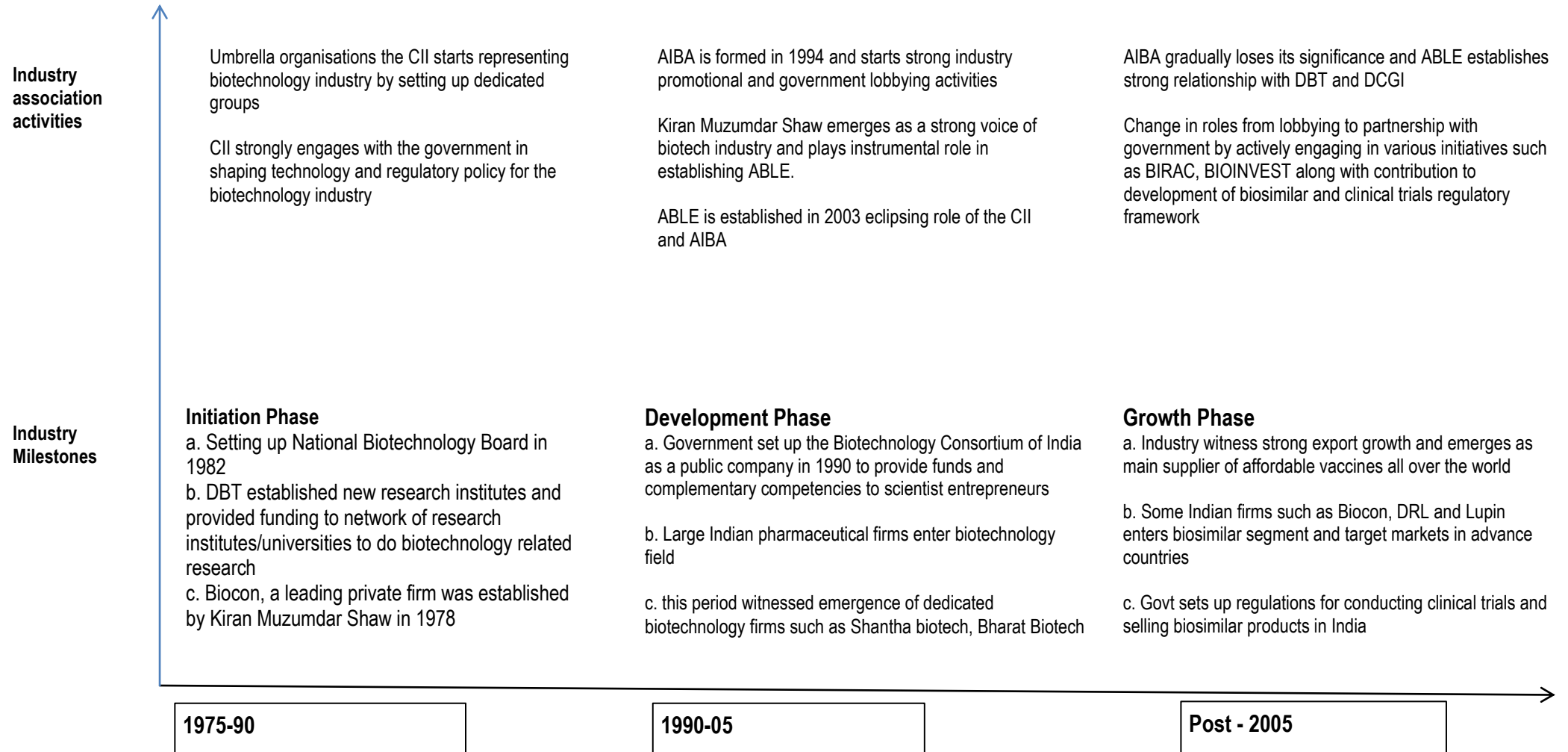


Fig 6 Evolution of the Indian medical device industry and role of industry associations

