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# **The Role of Industry Associations in Health Innovation and Politics of Development: the Cases of South Africa and India**

## **1. Introduction**

Over the last 20 years, developing countries have witnessed the increased role of non-government actors such as industry associations and umbrella organisations (i.e. organisations representing multi-sectoral industry firms and associations) in the diffusion and governance of health biotechnology (Lyall and Tait, 2005; Jespersen, 2008; Lyall et al, 2009). The latter ‘...is becoming one of the driving forces behind economic development of developing countries and a vital tool for improving efficiency and accessibility of healthcare for the poor’ (Abuduxike and Aljunid, 2012: 2). Several developing countries with powerful industry associations, including India and South Africa, have made remarkable progress towards addressing local health needs through intensive research and development (R&D) and innovative health products (John, 2005; Jason, 2006; Mahoney and Morel, 2006). This is significant, as pharmaceutical and biotech companies based in developed countries have tended not to produce drugs for exclusive use in the developing world or to make significant investments in drugs for neglected diseases. Therefore, the role of developing country companies (i.e. domestic pharmaceutical and biotech companies as well as multinational corporations based in developing countries) in filling this gap is of huge importance. These companies and their associations can be regarded as the biopharmaceutical industry.

The rapid growth of health innovation in developing countries and the increased importance of biopharmaceutical industry associations in influencing innovative performance require new thinking about the institutions which diffuse and govern knowledge in emerging contexts of economic and political pluralism. This paper makes a novel, first attempt at establishing the extent to which biopharmaceutical industry associations and umbrella organisations promote the development of technological capabilities and effective governance of health innovation; raising pertinent questions for further investigation, and laying the groundwork for future research in this area. Comprised as a pilot study, this research is based on data gathered through fieldwork that focused on the activities of five associations in India and South Africa. These data suggest that sector specific industry associations constitute public actors which play key roles in the politics of innovation and development of both countries. The data further reveal that sector-specific industry associations and umbrella organisations clearly engage differently with government and policy makers; the former function more as an ‘interface’ of its members or as an ‘extension’ of the industry while the latter perform the role of an ‘intermediary’. This distinction has significant implications not only for policy makers involved in shaping Indian and South African innovation policies, but also for organisations which play crucial roles in health innovation diffusion. Despite differences, biopharmaceutical industry associations and umbrella organisations in India and South Africa not only diffuse knowledge to health innovation systems but also actively engage in an upstream relationship with government, influencing innovation policy and regulations. This relationship is often uneven in the sense that there are conflicts of interests and discontinuities which determine innovation policy and regulation.

This paper is divided into five sections. Section 2 provides a conceptual understanding of biopharmaceutical industry associations as public actors for innovation and development. Section 3 presents the research methodology underpinning this paper. Section 4 focuses on the cases of India and South Africa, discussing the activities of five associations and umbrella organisations: CII and OPPI (India); IMSA and PIASA, and CHAMSA (South Africa). Section 5 discusses these cases in light of the conceptual framework and concludes by summarising the main argument.

## **2. Understanding Industry Associations as Public Actors for Innovation and Development**

Industry associations are often regarded as controversial actors of innovation and development. Several economists and political scientists express distrust in them. For instance, as early as the 18th century, Adam Smith (2003), in his book *The Wealth of Nations*, accused industry associations of playing a negative role in the economy, conspiring against the public or raising the prices of goods. In his view, associations were rather enemies of the emerging liberal market and the process of free competition. Much later, Mancur Olson (1982) argued that industry associations always seek unproductive rents rather than pursue the common or public interest. His theory was based on a study of *The Logic of Collective Action* where he insisted that ‘...unless the number of individuals in a group is quite small, or unless there is coercion or some other special device to make individuals act in their common interest, rational self-interested individuals will not act to achieve their common group interests’ (Olson, 1965: 2). Taking on board this theory, Moore and Hamalai (1993) warned that industry associations can even generate conflict and lead to waste of resources instead of promoting entrepreneurship and innovation. The rent-seeking activities of associations and their competition for influencing governmental action enable them to adopt differentially advantageous positions. This, in addition to conflict and waste of resources, can also affect the degree of democratisation of a country (Kimenyi, 1989). When the state and government are penetrated by industry associations and other sectoral interest groups, administrative authority is required. In this way, policy makers see associations and groups as their clients, trying to satisfy their needs rather than promoting the interests of the public (Atkinson and Coleman, 1989).

However, despite criticism, lobbying of governments continues to be a widespread practice in capitalist economies (Bouwen, 2002). Industry associations are institutional developments which create ‘state-society synergy’. According to Evans (2011) that synergy was crucial to 20<sup>th</sup> century industrial transformation. In the current century, interest in industry associations and their role in accelerating innovation and economic prosperity will grow in developing countries (Nadvi, 1999). The reason for this is that industry associations are key policy making actors. As Granovetter (1995: 96) points out ‘...their activity has to do less with operations and more with negotiating and affecting the institutional and governance arrangements under which their industry proceeds’. Greenwood and Hinings (1996) indicate that industry associations can work closely with the state to protect their self-regulating independence and autonomy as governments not only have control over some resources crucial for firms’ survival, but also influence their innovative capabilities

through specific regulations e.g. intellectual property rights (IPRs) and innovation policies (Halpin et al, 2011; Baines and Viney, 2009). In some situations, the state will collaborate with such associations to rationalize an arena of activity or tap their expertise in developing new governance frameworks (Scott, 1992, p. 211).

At the very least industry associations provide a forum, allowing companies to come together and collectively discuss issues of innovation and economic development (Nadvi, 1999). According to Foray (2009: 372) ‘Collective action in the domain of innovation and technology is a key issue. There are a large number of economic opportunities for collective action – not only in some pre-competitive areas of scientific research but also in many highly competitive markets’. Foray focuses on what he calls industry-specific public goods (ISPGs) i.e. resources that are public and industry specific e.g. particular set of skills, class of capital good equipment, technical services, etc. For him, industry associations constitute solutions to the problem of provision of ISPGs. However, industry associations are socially and politically embedded institutions with functions which go far beyond ISPGs. This is so especially in developing countries and will be demonstrated in the next sections of the paper.

Recent empirical work on biopharmaceutical industry associations in developing countries (Athreya and Chaturvedi, 2007: 157) suggests that they ‘... fulfil important information and coordination roles ... often compensating for inadequacies in the business environment, when faced with the need to compete in external markets’. In addition to this, they develop networks and partnerships through which public-private collaboration for biopharmaceutical innovation can be achieved. The institutional context in which many biopharmaceutical industry associations operate in developing countries is one of ‘...inefficient policies and regulations, as well as ...weak linkages between the public and private sector. The latter shortcoming is largely the result of an inadequate national innovation system’ (Abuduxike and Aljunid, 2012: 2). Indeed, as Intarakumnerd and Charoeporn (2013) observe, in a number of developing economies, innovation systems can be characterised as weak and fragmented because of high degree of such systemic failures. Many association activities are designed to improve the functioning of government in terms of efficient policies and regulations. It is clear that industry associations play an important role in shaping government policies on innovation, establishing governance institutions and strengthening the enforcement mechanisms. Therefore, they need to be carefully understood in terms of more interdisciplinary frameworks such as those of national systems of innovation (Lundvall, 1992; Nelson, 1993; Edquist, 1997; Freeman and Soete, 1997) and politics of development (Lucas, 1997; Houtzager and Moore, 2003; Williams, 2004; Leftwich, 2005; Hickey, 2008; Papaioannou, 2011).

Industry associations are institutions (North, 1990) which appear to be actively involved in the diffusion of knowledge within health-innovation systems of developing countries. According to Abuduxike and Aljunid (2012: 2) ‘A national health-innovation system consists of such dynamic networks of public and private sectors, connected through nonlinear interactions and activities to generate specific knowledge and use it to produce and supply new technologies [and products] to solve health problems’. A country’s NSI in general and national health-innovation system in particular depend on politics of development, i.e., the process of establishing governing structures and institutional environments within which interactions take

place. Such structures include stable regimes, financial system, innovation policies and research and education systems (Chaturvedi, 2007).

Recent research (Doner and Sheneider, 2000) suggests that in developing countries the political creation of successful institutions of innovation happens only under significant pressure from actors such as industry associations. According to Tsebelis (2002), industry associations constitute ‘veto players’ which influence politics of development and therefore governing structures of biopharmaceutical innovation capabilities. For example, concerns about infrastructure and service improvements are advanced by associations through a combination of direct action and lobbying. In countries such as India that exhibit strong politics of development (Abuduxike and Aljunid, 2012) biopharmaceutical industry associations appear to engage in public action towards improving institutional environments and assisting firms in strengthening technological capabilities. In countries such as South Africa that exhibit less strong politics of development, biopharmaceutical industry associations appear to engage in public action towards building a NSI.

Although innovation and governance have been traditionally treated as distinct activities from politics, the interdisciplinary frameworks of NSI and politics of development begin to recognise that getting politics right is, if not a precondition, at least a requisite of technological innovation and good governance. To put it another way, this paper, attempts to re-politicise innovation and governance (Williams, 2004) drawing attention to the impact of lobbying on pro-innovation and pro-poor policy making. For doing so, this research explores the following overarching question: *In what way(s) do industry associations figure in shaping the diffusion agenda for health innovation in developing countries and in contributing to strategies for sustained and inclusive economic growth?* Given that technological innovation is key to poverty reduction (Kaplinsky et al, 2009), it follows that government and civil society are crucial for enabling the formulation of appropriate innovation programmes and governance schemes (i.e. programmes which promote innovation capabilities building) in the area of health innovation.

### **3. Research Methodology**

This paper is based on an empirical study of biopharmaceutical industry associations and umbrella organisations in middle-income developing countries. The overall methodological approach here is qualitative cross-national comparison. The focus is on two countries: India and South Africa. India was selected as one of our empirical research sites because of its active involvement in health innovation and its pluralist context that allows strong policy input from non-state actors such as biopharmaceutical industry associations (Athreye and Chaturvedi, 2007). India also has a well-established knowledge-driven pharmaceutical industry (Abuduxike and Aljunid, 2012), becoming ‘...one of the world’s largest suppliers of vital medicines and vaccines’ (Srinivas, 2012: 10). From only 2003 to 2005 it is estimated that India’s biopharma economy grew by 30%. During that period the top 10 pharmaceutical companies in India spent more than Rs9.7 billion (US\$155 million) on R&D (Satyanarayana, 2007). A number of these companies are represented by the Organisation of Pharmaceutical Producers of India (OPPI) and the Confederation of Indian Industry (CII). For this reason OPPI and CII were selected as specific cases of biopharmaceutical and umbrella associations.

South Africa was identified as our second empirical research site because of its recent entry into the biopharmaceutical industry and its introduction of a NSI approach that allows interactions between different actors, including government and industry associations. A recent National Biotech Survey revealed more than 106 biotechnology companies in South Africa, including 47 identified as ‘core’ biotechnology firms, and more than 154 biotechnology products and/or services with earning revenues of at least US \$61 million per year? The majority of these companies and products are in human health (Cloete et al, 2006: 559). This is because South Africa in particular and Sub-Saharan Africa in general are unique in terms of requirements for pharmaceutical products which combat diseases such as HIV/AIDS and Tuberculosis. South Africa’s expenditure for healthcare amounts to approximately 8% of gross domestic product (GDP) (IMSA, 2012). Biopharmaceutical companies in this country are members of both sector specific and umbrella organisations. On the one hand, the Pharmaceutical Industry Association of South Africa (PIASA) is a sector specific organisation that until recently represented domestic but also foreign multi-national biopharmaceutical companies (MNCs). In 2009 its members supplied about 40% of the total pharmaceutical market in South Africa (PIASA, 2009). However, in April 2013 PIASA merged with Innovative Medicines South Africa (IMSA). The latter used to represent research-based companies. The new association was named Innovative Pharmaceutical Industry Association South Africa (IPASA). At the time of writing this paper there is limited information about the activities of IPASA. Therefore our analysis is historical, focusing on its constituent associations i.e. PIASA and IMSA. On the other hand, the Chambers of Commerce and Industry of South Africa (CHAMSA) is an umbrella organisation that represents multi-sectoral companies, including biopharmaceuticals. The reason for selecting PIASA and IMSA (IPASA) and CHAMSA as specific cases of associations is their wide representation of both domestic companies and MNCs.

Data for this paper was collected through research involving OPPI, CII, PIASA and IMSA (IPASA), and CHAMSA. From July 2011 to December 2013 relevant documents e.g. reports and web-based publications of these associations were collected. In addition 12 face-to-face interviews were conducted with key respondents in India and South Africa. The interviews lasted 20 to 60 minutes with a mean duration of 30 minutes. Interview questions focused on the context and historical background of OPPI, CII, PIASA and IMSA, their main activities, their role in the interface between innovation, knowledge and politics, their function as public actors and co-ordination institutions of politics of development. Empirical data was analysed in terms of the conceptual framework of innovation and governance, revealing the role of biopharmaceutical associations in knowledge and innovation diffusion. Table 1 provides an overview of the pharmaceutical associations and umbrella organisations studied for this paper.

Table 1: Industry associations under study

No	Name of Industry association	Year of establishment	Type of industry association	No. of members	Nature of membership

1	CII (India)	1895	Umbrella	7100	Dominated by technology firms
2	OPPI (India)	1965	Sector specific	93	Dominated by MNCs
3	CHAMSA (South Africa)	2003	Umbrella	<600,000	Dominated by multi- sectoral firms
4	PIASA+IMSA (IPASA) (South Africa)	2003 (2013)	Sector specific	90 + 14 (24)	Dominated by MNCs

*Source: Table developed by authors from study data*

#### **4. The Cases of India and South Africa**

##### ***India***

Over recent decades, the growing economic and political power of India, one of the so-called BRICS, has attracted substantial attention (Wilson and Purushothman, 2003). Researchers tend to investigate the drivers of India's economic growth and its implications for global governance and development. However, what they often overlook is that India is the world's largest democracy and this has implications for the state-industry relations. According to Kohli (2001: 1) 'Indian democracy is ...best understood by focusing, not mainly on its socioeconomic determinants but on how power distribution in that society is negotiated and renegotiated'. A concern with power distribution and negotiation/renegotiation of interests draws attention to the role of industry associations in governing innovation and development through lobbying of government.

The diversity of interests is reflected in the emergence of different types of industry organisations. For example, in India there are three dominant umbrella industry associations: Confederation of Indian Industry (CII), Federation of Indian Chambers of Commerce and Industry (FICCI) and the Associated Chamber of Commerce and Industry of India (ASSOCHAM). These organisations have established extensive presence and membership in the Indian industrial and economical policy environment. Each of these organisations claims to be the main representative of Indian industry at different national and international forums. One key respondent claims that FICCI has more grassroots presence and more political influence than does CII. However, this statement is contradicted by a key respondent from CII who insisted:

...the association has significant influence in shaping government policies and regularly interacts with various arms and policy making (interview extract 1).

A clear distinction is witnessed in their historical evolution, policy agendas and membership. For example, each organisation has developed different views on the economic liberalisation process and took a different position on policies based on that. CII has been credited with supporting government's economic liberalisation policies

even though increase of competition from overseas companies would have affected its members while FICCI and ASSOCHAM were criticised for opposing liberal reform agendas. One respondent explains:

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 and its leadership represented regressive face of the industry (interview extract 2).

Moving on to industry specific associations which represent the Indian health sector, similar differences can be witnessed. For example the Indian biopharmaceutical industry is represented by three different organisations: Organisation of Pharmaceutical Producers of India (OPPI), Indian Drug Manufacturers Association (IDMA) and Indian Pharmaceutical Association (IPA). Each of these organisations represents interests of particular group of firms; OPPI membership is dominated by MNCs, IDMA represents small and medium sized domestic firms (SMEs), IPA works as a business organisation and members include the top 11 India firms.

It is quite clear that these industry specific associations compete but, in some cases, also collaborate to influence policy. This competition and collaboration create certain challenges for industry associations. These challenges, particularly the positioning of association leadership and the collection and diffusion of information, become more apparent when looking at the cases of India's OPPI and CII in more detail. Timing also appears to be important. In terms of politics of development, the timing of putting demands to government for biopharmaceutical innovation seems to be thought in relation to who is in power in which ministry.

### *OPPI*

OPPI is a sector specific association, representing the interests of the Indian biopharmaceutical industry. The association was established in 1965 as a premier association of research and innovation driven pharmaceutical companies in India. In total OPPI has about 74 members out of which 55 are core members (mainly MNCs) and 19 associated members (mainly Indian domestic firms). It has strict entry barriers and not any biopharmaceutical company can join OPPI. According to one respondent:

OPPI membership is not automatic and only those members are allowed that respect intellectual property laws, follow global standards in terms of manufacturing and clinical practises and finally adopt transparent marketing code. Existing members have to approve the addition of any new member (interview extract 3).

As such, membership of OPPI comes with several obligations for companies: Biopharmaceuticals have to follow good manufacturing practices (GMP) and OPPI's code of pharmaceutical practices (GCP), as well as adhere and support OPPI's position on intellectual property rights (IPRs). Respect for strong IPRs is one of the four issues that OPPI focuses on and promotes policy. The other three are: adherence to a marketing code similar to that of the fast moving consumer goods (FMCG) sector; global standards of operations for all companies operating in India; and corporate social responsibility. OPPI promotes these issues through direct and indirect



participation in India's policy making. Overall, the association favours strong IPR protection laws, wants strict GMP/GCP and supports a transparent marketing code.

In order to influence policy making, OPPI actively seeks representation in a number of government bodies. For example, its president is a member of the Indian planning commission and has made presentations to government ministers. According one respondent OPPI strongly influenced government's decision to introduce strong IPR laws in India as part of TRIPS agreement:

OPPI spearheaded the movement towards strong IPR laws in India. We made presentations to government ministers, provided evidence of its benefits and created awareness among key government decision makers (interview extract 4).

In some cases the association works in partnership with government to implement policy among members. For example, in the case of GMP (good manufacturing practices), OPPI lobbied government for the development and implementation of such laws, representing the interests of MNCs. Similarly, OPPI works with government in setting up biosimilar regulatory and transparent marketing guidelines.

Another policy area that OPPI aims to influence government is less restriction on foreign direct investment (FDI) in pharmaceutical industries. One respondent emphasises:

OPPI works hard to create a conducive environment for business. Our key focus is to ensure access to medicines for all, create an ecosystem for innovation and facilitate development of global standard manufacturing base and transparent marketing practises (interview extract 5).

OPPI also promotes international cooperation of pharmaceutical companies. This is through its membership of the *International Federation of Pharmaceutical Manufacturers and Associations* (IFPMA). Similarly, OPPI selects perspectives from other countries and 'cherry-picks' appropriate policy initiatives to promote in India. According to one respondent for OPPI:

the association is in direct contact with similar overseas organisations, especially in the United States (US) and Europe and thus have access to inside information (interview extract 6).

The importance of international cooperation for biopharmaceutical industry associations is not just gaining access to 'inside information' but also building alliances with powerful international lobbies and actors to influence global and domestic policies.

## CII

As has been said, CII represents other smaller associations and industries. CII was founded in 1895, when five engineering firms, all members of the *Bengal Chamber of Commerce and Industry*, joined forces to form the *Engineering and Iron Trades Association* (EITA). Over the years the association has undergone various name changes following the evolution of the Indian industrial environment but always representing engineering industries. After India's economic liberalisation in the 1990s

the association became CII, representing inter-sectoral integration. Such integration becomes possible through a process of diversification and expansion of industries in a way that better represents different interests and complexities within an industry.

CII is currently India's premier business association. It has a direct membership of over 7100 organisations from the private as well as public sectors, including biotech SMEs and pharmaceutical MNCs, and an indirect membership of over 90,000 companies from around 250 national and regional sectoral associations. In 1990 CII rose to prominence by supporting the economic liberalisation agenda initiated by the Indian government at that time. Unlike other umbrella industry associations CII provided extended support to government in initiating reform process. One respondent commented:

CII played a really valuable role in early reform process. If you talk to Montek Singh Ahluwalia, he ... says that CII was a strong voice in reform and even when some of its members' interests would have hurt in short time, CII argued in favour of opening of the economy, reduction of tariffs and integration with the World economy (interview extract 7).

CII has a separate dedicated unit representing technology based firms and is involved in organising technology focused conferences, workshops and trade missions. Such activities of knowledge provision are in line with CII's principle objectives which are to provide information, advisory, consultive and representative services to industry and government. One respondent explains:

...industry associations [such as CII] do play a role in innovation diffusion provided one defines innovation broadly. The definition I like to use is something new and for commercial advantage. It applies to process, it applies to product; it applies to something that gives you commercial advantage (interview extract 8).

The association operates through national/regional/state/zone councils. It has specialised industry divisions such as biopharmaceuticals and affiliated associations such as OPPI. One respondent argued that umbrella organisations such as CII have different agendas than sector specific organisations and a far more challenging role of balancing views of different interests groups. He explained:

A sector specific organisation is a tremendously narrow service membership body and the interest of its members tends to be more allied because they do the same thing ... CII as an umbrella body represents more industries. In this case ... you could argue that industry associations should not lobby for interests or anything that will benefit any particular firm ... The role of industry associations should [be to] lobby for changes that will benefit industry ... (interview extract 9).

In terms of policy involvement, CII representatives sit on all major policy making bodies of India, focusing on industrial development and innovation. Another respondent provides an example to explain the role CII plays in influencing government policy:

First, I think CII played a good role in government's weighted deduction policy for all R&D expenditure in the pharma industry, many years ago, then it was extended to auto and auto component industry. That was thanks to an argument and case made by

CII. Subsequently two years ago it was extended to all industry based on the argument and case that we made in the CII (interview extract 10).

One key role of CII is also promoting international industrial co-operation. It identifies and addresses specialised needs of the SMEs sector. For example, CII's International Division provides services through networking with Indian missions overseas and over 45 counterpart organisations throughout the world. The association provides up-to-date information to both government and industry on a number of topics. Post 2010 CII has established an "Innovation Council" and has been involved in the development of innovation metrics that are appropriate to the local context.

In addition to this, CII also organises specialised fairs, including the 'Indian Engineering Trade Fair', and it publishes a number of reports and bulletins concerning the economy, industry, business and innovation. In this way, CII diffuses macro level information to not only a broad industry constituency, but also government and its various agencies; thus strategically positioning itself between these two institutional actors.

From our analysis so far, it becomes apparent that associations such as CII are filling institutional gaps in developing countries with substantial impact on government competencies for tackling institutional corruption. This is also clear in the case of South Africa.

### *South Africa*

South Africa is also one of the BRICS. The country made the transition from an apartheid state to a constitutional democratic state in 1994. Since then South Africa has experienced exceptional economic growth performance but also increased inequality and extreme poverty in certain sections of the population. One key element of the South African politics of development is the relationship between the state and civil society. This relationship is characterised by vibrant interest groups and industry associations making claims on the state about two main issues: firstly, capability expansion through co-production of goods and services; secondly, increased share of resource revenues for investment in innovation and development (Evans, 2011; Heller, 2011; Arrighi et al, 2010).

Today in South Africa there are four dominant umbrella associations: the Afrikaanse Handelsinstituut (AHI), the Foundation for African Business and Consumer Services (FABCOS), the National African Federated Chambers of Commerce and Industry (NAFCOC) and the South African Chambers of Commerce and Industry (SACCI). These organisations play important roles in South African industrial innovation and politics of development. AHI is a multi-sectoral association with branches in all 9 provinces of South Africa. This association supports market-driven economy. FABCOS is an association for SMEs from different sectors. NAFCOC is an umbrella association primarily serving the black community. SACCI is an association of technology based firms from different sectors, including biopharmaceuticals. Despite the clear differences between these associations, they are all represented by CHAMSA, the wider umbrella organisation in South Africa.

Similar differences can be identified between biopharmaceutical industry specific associations such as PIASA and IMSA (before their integration). Each of these associations represents particular interests of biopharmaceutical firms. Let us now analyse the cases of PIASA and IMSA, and CHAMSA in more detail.

#### *PIASA+ IMSA (IPASA)*

As has been already mentioned, in April 2013 PIASA and IMSA merged to form a new sector specific association called IPASA. The latter currently represents 24 companies dedicated to producing innovative medicines in South Africa. According to IPASA, only companies that conduct their own R&D qualify for membership. This means that domestic companies with no IP are excluded from the new association. Only IP holders e.g. MNCs can become members of IPASA. The vision of this new association is to create an environment of pharmaceutical innovation and excellence. IPASA is focused on access to healthcare, investment in R&D, IPRs and standards. In addition, it is a member of IFPMA and has access to global health innovation.

IPASA is currently in an uneven negotiation with government over the latter's policy plan to change its rules for medicine patents. That plan incorporates patent flexibilities after the Doha Declaration (WTO, 2001) and recommends elimination of weak patents, promoting the production of generics (DTI, 2013). In response, IPASA appears to be embarked on a campaign against the full implementation of the government plan, lobbying the government and other national and international actors for a stronger IPR regime. Its main objection is that, by using TRIPS flexibilities and by promoting generics, the South African government's plan on IP policy will reduce innovation and fail to attract investment, particularly FDI, into knowledge-based firms such as those in biopharmaceuticals (IPASA, 2013). Given the ongoing negotiation and the lack of empirical data about IPASA, what proceeds is a historical analysis of its constituent associations: PIASA and IMSA.

PIASA was established as an association of companies involved in the manufacturing and marketing of medicines in South Africa. Its members were of two types: research-based MNCs; and local manufacturers of pharmaceuticals. PIASA until recently had about 90 members, consisting of both large and small companies. According to one respondent, the membership could be higher:

...but we require a membership fee<sup>1</sup> every year, while some companies see no need to be part of associations such as ours ... hence this is the membership we have. Sadly, we cannot stop non-members from benefitting from our efforts down the line (interview extract 11).

Other organisations, such as the South Africa Medical Device Industry Association (SAMEDI) were members of PIASA, testifying to the diversity of the association. The objective of PIASA was to shape strategic regulatory issues relating to clinical trials, registration of medicines and IPRs. These issues determine innovation in the biopharmaceutical sector of South Africa. More specifically, PIASA had been trying to tackle regulatory hurdles that discourage investment in South Africa's biopharmaceutical sector. One respondent was categorical:

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<sup>1</sup> This was said to range from 30 thousand to 6 million South African Rand per year for small to larger companies respectively (US\$3000 to US\$0.5million)

...it cannot be emphasised enough that poor intellectual property protection discourages pharmaceutical investment in Africa (interview extract 12).

In addition to this, PIASA was also engaged in activities to influence the quality and cost of medicines, access to treatment, health insurance, drug laws and pharmacoeconomic evaluation. Among such activities advocacy, networking and innovation diffusion appear to be the most crucial ones.

PIASA interacted with government but also with other associations, including the recently integrated IMSA in the health policy and regulation arenas. For instance, it had substantial involvement in the formulation of the South African Health Charter and Private Health Care Reform programmes. This close interaction of PIASA with government was often seen as uneven, given the conflict of public and private interests, but according to PIASA:

...our location necessitates that we should understand the interests and positions of both our members and of government. We have to understand rules on both sides (interview extract 13).

As a result of this delicate balancing act, the association had been clearly acknowledged to be a critical factor for pharmaceutical development and innovation, ensuring that the industry's voice is heard and that required standards are met by both industry and government. PIASA's points of contact in government were mainly the Pricing Unit and Medicines Control Council.

One of the most important activities for PIASA was diffusion of knowledge. The association would often hire consultants to provide members with expert advice on pertinent issues in the health innovation and regulation terrains. Such issues include: standards for manufacturing facilities, drug registration fees, regulatory harmonisation, etc. As one key respondent for PIASA stressed:

We have to be proactive to be able to deal with the diverse needs of our 90 members ... researching, benchmarking, advising, lobbying, negotiating on business practice, government affairs, clinical trials, health outcomes, scientific regulatory issues and so on (interview extract 14).

Such a range of activities in the institutional context of South Africa indicates that PIASA played a crucial role in influencing the country's innovation system. For example, it contributed to curriculum design for training of pharmacists and other graduates destined for employment in the pharmaceutical sector. As another key respondent for PIASA said:

We are realising that the health system and its demands are much wider than envisaged. We have to constantly reflect on what we can realistically do in order to meet the needs of our members (interview extract 15).

An up to date curriculum and training for pharmacists are clearly some of these needs. PIASA was also consulted and played an active role in formulating South Africa's multi-sectoral 10-year innovation plan (2008-2018). It was active in implementing

one of the pillars of the plan which aims to address the perceived ‘innovation chasm’ between research results and innovation benefits.

PIASA not only served as a ‘landing pad’ for domestication of international manufacturing standards as required by IFPMA and the World Health Organisation (WHO) but also contributed to bringing and strengthening health innovation in cross-national arenas. As one respondent noted:

We have worked with the New Partnership for Africa’s Development (NEPAD) on regulatory harmonisation and have also been advocating for health to be a key issue in the North-South corridor programme which seeks to facilitate trade in Eastern and Southern Africa (interview extract 16).

Now let us turn to IMSA. As has been already mentioned, this was an industry association for research-based companies even though some of its members also produce generics. This is not surprising. South Africa engages in R&D, manufacturing, sales and marketing not only of branded drugs but also of generics. The latter are crucial for the public health service in the country. Among IMSA’s members were 12 MNCs who captured about 53% of the MNC market share in South Africa. Generally speaking, this biopharmaceutical association engaged in three main activities: R&D policy, innovation regulation and lobbying. On policy, one respondent summed it up thus:

...we interpret policy for our members and make submissions on policy to government’ (interview extract 17).

IMSA did not always perform such activities alone but in collaboration with other associations. Thus, for instance, IMSA played an active role in national health insurance issues, working jointly with PIASA (for a long time before they merged) and other public actors of the South African system of innovation.

In South Africa, industry associations work together under the umbrella of the National Pharmaceutical Task Group. Examples include the joint action for development of the Marketing Code and the Health Charter. The objective of industry associations’ collaboration in the South African biopharmaceutical sector is mainly to provide industry with specific public goods.

Given that the biopharmaceutical industry is heavily regulated, reducing the time of registration and delivery is paramount to innovation and health system performance. This implies reducing the regulatory burden for drugs without compromising their safety, quality and efficacy. Another key focus of IMSA was on IPRs, especially access to drugs (for poor patients) and marketing. The association worked with and through their members to exert influence on these issues. Finally, IMSA was involved in the South Africa’s new National Health Insurance (NHI) policy, shaping its development and 14-year period of implementation.

IMSA’s key contacts in government used to be the South African Department of Health, the Department of Science and Technology and the Department of Trade and Industry. It also made policy contributions to parliament’s portfolio committee on health. However, IMSA also functioned as a government tool for industrial policy implementation. Specifically, it worked closely with government for the

implementation of broader national policies by their members e.g. requirements under the Black Economic Empowerment (BEE) programme. IMSA tried to engage government, and saw legal recourse as a last resort.

### *CHAMSA*

As has been mentioned, CHAMSA is an umbrella association. It has as its constituent members AHI, FABCOS, NAFSOC and SACCI. These members represent thousands of multi-sectoral firms, including biopharmaceuticals in South Africa.

CHAMSA was founded in 2003 with a mandate to create and sustain an environment friendly to businesses, facilitating economic empowerment and improving the conditions under which businesses operate in South Africa. Thus, it is clear that the focus and activities of this organisation is different from sector specific associations such as PIASA and IMSA. Particularly, CHAMSA is concerned with making economic governance more efficient and promoting industrial policies which support sustainable development. Therefore, this umbrella organisation works closely with government to develop and implement regulations which affect the innovative capabilities of thousand of companies in different sectors, including the biopharmaceutical sector.

The main guiding principle for CHAMSA appears to be market freedom. In this context, the organisation lobbies government for implementing minimum regulations and ensuring no interference with businesses. But as CHAMSA (2005: 2) states, this ‘...should not be without appropriate checks and balances, such as the Competition Commission. However, in the establishment of structures such as industry regulators, CHAMSA points out that it is of critical importance that while they may be appointed by government, they must be seen as completely independent and impartial, free from political interference and not as a quasi-government body’. This suggestion of impartiality is in line with CHAMSA’s liberal approach to market economy and government.

In terms of government policy involvement, CHAMSA directly provides input and feedback to government and parliament on various macro-economic policy issues. It promotes active engagement of businesses in consultative meetings. CHAMSA’s approach to policy and regulation, even though not in direct relation to PIASA and IMSA activities, enables biopharmaceutical industry specific regulatory initiatives about standards, marketing and time of registration and delivery of pharmaceutical products.

## **5. Discussion**

### *Emerging Pluralism*

Our case studies suggest that, in both India and South Africa, biopharmaceutical industry associations are formed as public actors which, on the one hand, provide their members with ISPGs and on the other influence innovation policy and politics of development. The economic and political context within which their activities take place seems to be that of ‘emerging pluralism’. The latter is a dynamic context of bargaining between competing interests and values (Dahl, 1989). Such interests and

values are advocated by formal associations of civil society (White, 1993). These public actors exercise power over politics of development and systems of innovation in developing countries.

It might be argued that in both India and South Africa pluralism formally emerged in the 1990s. In India the economic and political reforms which took place in that decade created the pluralist space for biopharmaceutical associations and other civil society organisations to negotiate power and lobby governments for pro-innovation regulation and governance (Corbridge, 2009). To put it another way, pressure was put on government for innovation friendly institutional reforms. Although it is true that the Indian democracy has never been insulated from associations and interest groups, it is also true that these public actors have become more influential on the country's innovation system since liberalisation. As Basile and Harris-White (2000: 11) point out 'The era of liberalisation in India is not only an opening up of certain sectors of the industrial economy, it is also a moment at which the advancement of interests is greatly intensified'. One critique of this emerging liberal politics is that it leads India towards a chaotic process of industrial policy. Various interests compete for influencing the political process. The result of competition is certain power dynamics taking place in certain periods of time. For example, our data suggest that in order for specific policy reforms to go ahead there is a need for a politician or bureaucrat to get behind them.

Similarly, in South Africa, since the transition from apartheid to a democratic state, a new economic and political space has been created for negotiation and governance of innovation but also for co-operation between industries and government. Such co-operation appears to be crucial for developing and implementing the South African innovation system, increasing technological capabilities in biopharmaceuticals. Public action is always purposive collective action (Mackintosh, 1992). Therefore biopharmaceutical industry associations in India and South Africa have a clear purpose of serving the diverse needs of their members. Appropriate regulatory environment and knowledge diffusion are two of these needs. In order to satisfy them, our evidence shows that biopharmaceutical associations and umbrella organisations not only offer consultancy services and training in a number of knowledge and innovation related areas but also engage in government processes of regulation. These collective activities are crucial for developing firms' dynamic capabilities (Teece and Pisano, 1994) and for helping them to co-ordinate changes in their challenging environment.

### *Upstream Engagement*

Our data so far is able to confirm that biopharmaceutical industry associations in developmental contexts such as those of India and South Africa play dual institutional roles. On the one hand, they engage upstream to lobby government for provision of ISPGs and regulatory issues such as IPRs. They do so through their direct participation in government committees and forums for innovation policy. The aim is for biopharmaceutical associations to get their views on the policy agenda, influencing the executive part of government (Nelson, 2000). Indeed, as Cavazos and Szyliowicz (2011: 476) confirm 'Associations will often work to set the agenda while simultaneously aiming to build awareness, influence policy-makers and gain favourable legal decisions. They will finally strive to ensure that their successes are



not dissipated in the implementation stage and that favourable state policy is enforced and effectively implemented. In this sense, associations can act as regulatory agents in that they seek to use the power of the state through legal activity'. In developmental contexts such activities appear to strengthen institutional development and positively affecting industry conditions. The threat biopharmaceutical industry associations are confronted with seems to be the lack of institutions and framework conditions for new knowledge development and health innovation (e.g. regulatory delays in the registration of new medicines).

On the other hand, biopharmaceutical industry associations in developmental contexts constitute policy instruments of governments. This goes beyond corporatism (Cawson, 1982) and towards co-regulation or joined-up governance. For instance, as our case studies suggest, both OPPI and PIASA used to co-regulate with governments, ensuring that their members would implement the regulations. Implementation of co-regulated policies and practices is a membership condition for some pharmaceutical associations in developing countries. Therefore, governments do not need to spend more resources in order to enforce implementation of regulations. Biopharmaceutical industry associations also provide policy input to governments for negotiating international agreements such as TRIPS (Athreye and Chaturvedi, 2007).

#### *Downstream Engagement*

Biopharmaceutical industry associations not only engage upstream, working closely with the state and governments to promote specific regulations and provision of ISPGs, but also they engage downstream, developing partnerships and/or coalitions with other associations for the achievement of common objectives. According to Cavazos and Szyliowicz (2011: 475) 'Coalition building is particularly effective in many settings since it is characterised by strategies that expand association resources and capabilities by finding interest groups with common perspectives on an issue that concerns the industry...the more powerful the coalition the more effective lobbying efforts are likely to be'. Especially in South Africa but also in India our data suggest that such coalitions are strong, indicating common perspectives across different industrial sectors. Umbrella organisations such as CII work together with OPPI to improve the domestic framework conditions for knowledge diffusion and technological innovation.

Coalitions and partnerships transcend national borders. That is to say, biopharmaceutical associations of developing countries increasingly develop coalitions with biopharmaceutical associations and other lobbying groups of developed countries but also global public actors like IFPMA. These coalitions not only put pressure on global institutions such as the WTO as regards global health governance but also create knowledge of global governance and provide platforms for domesticating good practices of manufacturing and distributing drugs. Learning from global experience appears to be a key benefit of the involvement of Indian and South African associations with IFPMA.

## **6. Conclusion**

This paper has sought to examine for the first time the role of biopharmaceutical industry associations in health innovation and politics of development, focusing on

India and South Africa. The argument has been that such associations constitute public actors which not only diffuse knowledge to national innovation systems but also engage upstream in uneven relationships with governments and downstream in coalitions with other associations. The economic and political context within which biopharmaceutical industry associations operate in India and South Africa is that of emerging pluralism. In both countries pluralism not only enables biopharmaceutical associations and their umbrella organisations to collaborate for advancing common claims to government but also for becoming government instruments themselves for innovation and development. This dual role of biopharmaceutical associations and umbrella organisations makes them less neutral politically but more effective institutionally. In a number of respects, they co-develop policies and regulations which impact on health innovation. Therefore, their innovative and political role should be seriously taken into account in the sector of health care.

As has been already mentioned, this paper is based on a pilot study of biopharmaceutical associations in India and South Africa. A large study of such associations is currently under way at the OU. This study will address a range of questions about the role of associations in influencing regulatory frameworks, the extent to which they co-ordinate the implementation of innovation policies, the extent to which they diffuse knowledge and build capabilities, etc. Research results will build on and go beyond the conclusions of this paper, seeding further light on this neglected aspect of innovation and politics of development.

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