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Theo Papaioannou\*, Andrew Watkins, Dinar Kale and Julius Mugwagwa

# Industry associations, health innovation systems and politics of development: the cases of India and South Africa

**Abstract:** Over the last 20 years, developing countries have witnessed the increased role of non-governmental actors such as health industry associations and umbrella organizations in the diffusion and governance of health innovation. Utilizing extensive interviews with actors in the Indian and South African health industries, this paper argues that, in a context of emerging pluralism – i.e., a dynamic context of bargaining between competing (public and private) interests and values – these associations constitute public actors that play dual roles in the politics of innovation and development. Specifically, not only do they engage downstream by diffusing knowledge to their respective health innovation systems in order to achieve common objectives, they also engage upstream with their governments to co-develop policies and regulations. This dual role of health industry associations and umbrella organizations makes them less neutral politically but more effective institutionally, and their innovative and political role should be seriously taken into account in the healthcare sector.

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## 1 Introduction

Over the last 20 years, developing countries have witnessed the increased role of non-governmental actors in the diffusion and governance of health innovation such as industry associations and umbrella organizations – i.e., organizations

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representing multi-sectoral industry firms and associations.<sup>1</sup> 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.”<sup>2</sup> 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.<sup>3</sup> 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, and instead, the role of domestic pharmaceutical and biotech companies as well as multinational health corporations with facilities in developing countries – i.e., the health industry – has filled this gap.

The rapid growth of health innovation in developing countries and the increased importance of health industry associations in influencing innovative performance require new thinking about the private and public institutions which diffuse and govern knowledge in emerging contexts of economic and political pluralism. This paper makes a novel attempt at establishing the extent to which health industry associations and umbrella organizations promote the development of technological capabilities and effective governance of health innovation. Drawing on data gathered through desk-based research and fieldwork in India and South Africa, we argue that these associations constitute public actors that play key roles in the politics of innovation and development. The data further reveal that health industry associations and umbrella organizations clearly engage differently with government and related stakeholders; 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 policymakers involved in shaping Indian and South African innovation policies, but also for organizations which play crucial roles in health innovation diffusion. Despite differences, health industry associations and umbrella organizations in India and South Africa not only diffuse knowledge to health innovation systems – i.e., downstream engagement – but also actively engage in an upstream relationship with the government, influencing policies and regulations. This relationship is often uneasy in the sense that there are conflicts of interests and discontinuities between associations and government.

This paper is divided into six sections. Section 2 provides a conceptual understanding of health industry associations as public actors for innovation and development. Section 3 presents the research methodology underpinning this

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<sup>1</sup> See Lyall and Tait (2005); Jesperesen (2008); Lyall, Papaioannou, and Smith (2009).

<sup>2</sup> Abuduxike and Aljunid (2012: p. 2).

<sup>3</sup> See Mugabe (2005); Korenblit (2006); Mahoney and Morel (2006).

paper, and Section 4 focuses on the cases of India and South Africa, discussing the activities of several health industry associations and umbrella organizations. Section 5 discusses these cases in light of the conceptual framework, and the paper then concludes by summarizing the main argument.

## 2 Understanding industry associations as public actors for innovation and development

Industry associations are often regarded as controversial actors in innovation and development. Several economists and political scientists express distrust in them. For instance, as early as the 18th century, Adam Smith, in *The Wealth of Nations*,<sup>4</sup> accused 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 argued that industry associations always seek unproductive rents rather than pursue the common or public interest.<sup>5</sup> 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.”<sup>6</sup> Building on this theory, Moore and Hamalai (1993) warned that industry associations can even generate conflict and lead to a waste of resources instead of promoting entrepreneurship and innovation.<sup>7</sup> 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 democratization of a country.<sup>8</sup> When the state and government are penetrated by industry associations and other sectoral interest groups, administrative authority is required. Otherwise, policymakers might see associations as their clients, trying to satisfy their needs rather than promoting the interests of the public.<sup>9</sup>

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4 Smith (2003).

5 Olson (1982).

6 Olson (1965: p. 2).

7 Moore and Hamalai (1993).

8 Kimenyi (1989).

9 Atkinson and Coleman (1989).

Despite criticism, lobbying of governments continues to be a widespread practice in capitalist economies.<sup>10</sup> Industry associations are institutionalized forms of public action which promote the interests of business elites through close relations with the state. In this sense, they often create “state-society synergy.” According to Evans (2014), that synergy was crucial to 20th century industrial transformation.<sup>11</sup> Indeed, especially in developing regions such as East Asia, industrial-led “economic growth has occurred in contexts where there were strong collaborative relations between political and economic elites.”<sup>12</sup> Thus, it seems there is a possibility of growth-enhancing relations between state and business.<sup>13</sup> Such a possibility has renewed research and policy interest in state-business relations (SBR) in general and industry associations in particular. For instance, Cali and Sen (2011), Sen (2013) and Te Velde (2013) clearly argue that effective SBR not only matter for economic performance but also for efficient skills development, capital formation and high productivity.<sup>14</sup> Also, Leftwich (2009) stresses such relations should be viewed from a historical institutionalist perspective, recognizing their role in achieving common goals – e.g., economic growth.<sup>15</sup>

Notwithstanding the focus on SBR and their impact on economic performance, the above literature has so far overlooked the role of industry associations in technological innovation in specific sectors. Innovation can be broadly defined as an activity that leads to technological products and/or processes which are new to the market and/or new to the world. Since the 1780s, these products and/or services have ranged from industrial textiles, railways and electricity to medicines, automobiles, information and communication technology and, more recently, nanotechnology, genomics and biotechnology.<sup>16</sup> Innovation as such depends on the systemic interaction between public and private actors as well as the feedback mechanisms that exist between value chains and users.<sup>17</sup> This is what neo-institutionalist economists such as Freeman, Lundvall and Nelson<sup>18</sup> define as national systems of innovation (NSI): “The systems of interacting private and public firms (either large or small) universities and

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**10** Bouwen (2002).

**11** Evans (2014).

**12** Cali and Sen (2011: p. 1542).

**13** See Amsden (1989); Evans (1995); Maxfield and Schneider (1997); Doner and Schneider (2000); Doner, Hicken, and Ritchie (2009).

**14** See Cali and Sen (2011); Sen (2013); Te Velde (2013).

**15** Leftwich (2009).

**16** Freeman and Soete (1997).

**17** Chataway et al. (2009).

**18** See Freeman (1995); Lundvall (1992); Nelson (1993).

governance agencies, aiming at the production of science and technology within national borders.”<sup>19</sup>

It might be argued that industry associations are key actors of NSI. As Granovetter (1995) 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.”<sup>20</sup> Greenwood and Hinings<sup>21</sup> 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.<sup>22</sup>

At the very least, within innovation systems, industry associations provide a forum, allowing companies to come together and collectively discuss issues of innovation and economic development.<sup>23</sup> According to Foray, “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.”<sup>24</sup> Foray focuses on what he calls industry-specific public goods (ISPGs) – i.e., resources that are public and industry specific, for example, particular sets 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 actors with functions that go far beyond ISPGs. This is evident not only in NSI but also in sectoral systems of innovation (SSI) – i.e., systems of knowledge linkages and networks at sectoral level.<sup>25</sup> One of such systems is health. According to Chataway et al. (2009):

*[the] health innovation system...includes relevant aspects of macro environment of institutions, pertinent rules and procedures within national systems of innovation, the activities of health institutions within a national health system and the micro level innovation activities of individual companies and organizations involved in healthcare value chain including production, delivery, financing and research.*<sup>26</sup>

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19 Niosi et al. (1993: p. 212).

20 Granovetter (1995: p. 96).

21 Greenwood and Hinings (1996).

22 Halpin, Daugbjerg, and Scharzman (2011); Baines and Viney (2009); Scott (1992).

23 Nadvi (1999).

24 Foray (2003: p. 372).

25 Malerba and Orsenigo (2002); Malerba (2004).

26 Chataway et al. (2009: p. 12).

Recent empirical work on the role of industry associations in health innovation systems of developing countries suggests that they “fulfill important information and coordination roles...often compensating for inadequacies in the business environment, when faced with the need to compete in external markets.”<sup>27</sup> 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 health 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.”<sup>28</sup> Indeed, as Intarakumnerd and Charoenporn observe, in a number of developing economies, innovation systems can be characterized as weak and fragmented because of the high degree of such systemic failures.<sup>29</sup> Many industry 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 health 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 innovation systems<sup>30</sup> and politics of development. The latter is particularly concerned with the role of politics, governance and institutions in production and diffusion of new goods and services for improving the lives of people, especially in developing countries.<sup>31</sup>

Industry associations appear to be actively involved in the diffusion of knowledge within health-innovation systems of developing countries. According to Abuduxike and Aljunid, “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.”<sup>32</sup> A country’s NSI in general and national system of health innovation (NSHI) in particular depend on the politics of development – i.e., the process of establishing governing structures and institutional environments within which interactions take

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<sup>27</sup> Athreye and Chaturvedi (2007: p. 157).

<sup>28</sup> Abuduxike and Aljunid (2012: p. 2).

<sup>29</sup> Intarakumnerd and Charoenporn (2013).

<sup>30</sup> See Lundvall (1992); Nelson (1993); Edquist (1997); Freeman and Soete (1997).

<sup>31</sup> See Lucas (1997); Houtzager and Moore (2003); Williams (2004); Leftwich (2004, 2006); Hickey (2008); Papaioannou (2011).

<sup>32</sup> Abuduxike and Aljunid (2012: p. 2).

place. Such structures include stable regimes, financial system, innovation policies and research and education systems.<sup>33</sup>

Recent research suggests that in developing countries, the political creation of successful institutions of innovation happens only under significant pressure from actors such as industry associations.<sup>34</sup> According to Tsebelis (2002), industry associations constitute “veto players” which influence politics of development and therefore governing structures of health innovation capabilities.<sup>35</sup> For example, concerns about health infrastructure and service improvements are advanced by associations through a combination of direct action and lobbying. India, for example, where a history of politics of development is strong,<sup>36</sup> has health industry associations that engage in public action towards improving institutional environments and assisting firms in strengthening technological capabilities.<sup>37</sup> By contrast, in South Africa where the politics of development is weak, health industry associations appear to engage in public action towards building a NSI. Yet, in both countries, the engagement of health industry associations in public action depends on whether they can serve their interests through institutional change.

Although innovation and governance have been traditionally treated as distinct activities from politics, the interdisciplinary frameworks of NSI and the politics of development begin to recognize that getting politics right is, if not a precondition, at least a requisite of technological innovation and good governance. In other words, this paper attempts to re-politicize innovation and governance by drawing attention to the impact of lobbying on pro-innovation policymaking in the health sector.<sup>38</sup>

### 3 Research methodology

This paper is based on an empirical study of health industry associations and umbrella organizations in middle-income developing countries. The overall methodological approach here is a qualitative cross-national comparison with a focus on two countries: India and South Africa. India was chosen because of its active involvement in health innovation and its pluralist context that allows

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<sup>33</sup> Chaturvedi (2007).

<sup>34</sup> Doner and Schneider (2000).

<sup>35</sup> Tsebelis (2002).

<sup>36</sup> Abuduxike and Aljunid (2012).

<sup>37</sup> Tsebelis (2002).

<sup>38</sup> Williams (2004).



strong policy input from NSI actors such as health industry associations.<sup>39</sup> India also has a well-established knowledge-driven health industry<sup>40</sup> and has fast become “one of the world’s largest suppliers of vital medicines and vaccines.”<sup>41</sup>

Much of India’s recent high GDP growth – an average of 6.9% for the 7-year period from 2000 to 2007 with a high of 9.2% between 2006 and 2007 –<sup>42</sup> is driven by technological innovations in the manufacturing of health products such as drugs, pharmaceuticals, medical devices, etc. Despite the 2008 financial crisis, this sector witnessed reasonable stability, and furthermore, global R&D flows to India have been sustained.<sup>43</sup> Within the health industry, a number of companies within the Indian health innovation system are represented by industry specific associations such as the Organization of Pharmaceutical Producers of India (OPPI), the Association of Biotechnology Led Enterprises (ABLE) and the Indian Pharmaceutical Association (IPA). At the same time, umbrella organizations such as the Confederation of Indian Industry (CII) and the Federation of Indian Chambers of Commerce and Industry (FICCI) play a crucial role in promoting health innovation at the national level. Finally, government agencies such as the Biotechnology Industry Research Assistance Council (BIRAC), private consultancy companies such as Pricewaterhouse Coopers (PWC), research organizations such as SERUM Institute, multinational corporations (MNCs) such as Glaxo Smith Cline (GSK) and domestic companies such as Achira Labs constitute important stakeholders in the Indian health innovation system.

South Africa, on the other hand, was identified as the second empirical research site because of its position as a health industry fore-runner in Africa and its recent 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 the sector of health.<sup>44</sup> This is because Sub-Saharan Africa in general and South Africa in particular are unique in terms of requirements for health products which combat diseases such as HIV/AIDS, malaria and tuberculosis. South Africa’s expenditure for healthcare amounts to approximately 8% of its gross domestic product

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**39** Athreye and Chaturvedi (2007).

**40** Abuduxike and Aljunid (2012).

**41** Srinivas (2012: p. 10).

**42** Krishna (2013).

**43** *Ibid.*

**44** Cloete, Nel, and Theron (2006: p. 559).

(GDP).<sup>45</sup> Health companies in this country are members of both industry specific and umbrella organizations. On the one hand, the Pharmaceutical Industry Association of South Africa (PIASA) until recently represented domestic but also foreign MNCs. In 2009, its members supplied about 40% of the total pharmaceutical market in South Africa.<sup>46</sup> However, in April 2013 PIASA merged with Innovative Medicines South Africa (IMSA), which used to represent research-based companies. The new association was named Innovative Pharmaceutical Industry Association South Africa (IPASA). Other industry specific associations within the South African health innovation system include the National Association of Pharmaceutical Manufacturers (NAPM) and the South African Medical Device Industry Association (SAMED). Conversely, the South African Chambers of Commerce and Industry (SACCI) is an umbrella organization that represents multi-sectoral companies, including biopharmaceuticals. Finally, government departments such as the Department of Trade and Industry (DTI), public-private partnerships such as the New Partnership for Africa's Development (NEPAD) but also MNCs such as Pfizer and domestic companies such as Litha constitute the main stakeholders in the South Africa health innovation system.

Data for this paper were collected through both desk-based research and fieldwork. The latter took the viewpoints of all three types of innovation actors mentioned above – i.e., industry specific associations, umbrella organizations and related stakeholders. From July 2011 to June 2014, relevant documents such as reports and web-based publications of these actors were collected. In addition, 45 face-to-face interviews were conducted with key respondents in India and South Africa, which lasted 30–90 min with a mean duration of 40 min. 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 and South Africa. This study indicated innovative activities in healthcare delivery, revealing systemic interactions between associations, government and other stakeholders. It also identified key informants to be interviewed. Building on the results of the pilot study, the extensive desk-based research mainly analyzed annual reports/reviews of associations and the fieldwork focused on face-to-face interviews with high level representatives of health industry associations, umbrella organizations and related stakeholders. 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 analyzed in terms of our conceptual framework of innovation

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45 IMSA (2012).

46 PIASA (2009).

system and politics of development. Methodological decisions about what counted as evidence of “successful” diffusion of knowledge and innovation were taken 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.); specific knowledge and innovation broker activities of health industry associations; development of platforms of knowledge and innovation diffusion, including conferences, workshops, etc. 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. Tables 1–3 present an overview of the health industry associations, the umbrella organizations and the related stakeholders studied for this paper. In addition, they provide the number of people interviewed in each organization. The justification for choosing these actors and not others lies in the key role they play in the Indian and South African innovation systems.

## 4 The cases of India and South Africa

### 4.1 India

#### 4.1.1 Context and historical background

Over recent decades, the growing economic and political power of India, one of the so-called BRICS, has attracted substantial attention.<sup>47</sup> 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 the size of India’s democracy – the largest in the world – and the implications it has for state-business relations. According to Kohli, “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.”<sup>48</sup> A concern with power distribution and negotiation of interests draws attention to the role of industry associations in governing innovation and development through lobbying of government.

To understand this role, one should go back to the early years of independence when India started bringing together inherited businesses and political communities experienced with liberal procedures of parliamentary democracy.

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<sup>47</sup> Wilson and Purushothaman (2003).

<sup>48</sup> Kohli (2001: p. 1).

**Table 1:** Health industry associations under study.

Name of association	Year of establishment	No. of members	Nature of membership	No. of interviewees
OPPI (India)	1965	93	Dominated by MNCs	3 from OPPI
ABLE (India)	2003	270	Dominated by small biotech companies	2 from ABLE
IPA (India)	1939	10,000	Dominated by Indian pharmacists	1 from IPA
IPASA (South Africa)	2013	24	Dominated by IP holder MNCs	6 from IPASA
NAPM (South Africa)	1977	24	Dominated by South African generics firms	1 from NAPM
SAMED (South Africa)	1985	160	Dominated by South African manufacturers	1 from SAMED

Source: Table developed by authors from study data.

As Yadar points out, “by 1947, there were more than 1500 businesses and trade groups...in India.”<sup>49</sup> This marks an important difference from the SBR of other developing countries. Indeed, as Kochanek also reminds us, the development of associations and interest groups in India “has historically drawn upon liberal traditions of free association and pluralism rather than European, collectivist-public-law based corporatism.”<sup>50</sup> The case of CII is quite characteristic here. As one respondent from CII said:

*...we started as just a 5 company association in Calcutta...at the time British capital in Calcutta formed an association of engineering companies. So that expanded with British capital and a lot of things came under railways...Now when Indian capital came to fore they had exactly the same structure as the Indian Chamber of Commerce in Calcutta.<sup>51</sup>*

**Table 2:** Umbrella organizations under study.

Name of umbrella organization	Year of establishment	No. of members	Nature of membership	No. of interviewees
CII (India)	1895	7100	Dominated by technology firms	5 from CII
FICCI (India)	1927	250,000	Dominated by multi-sector SMEs	5 from FICCI
SACCI (South Africa)	2007	20,000	Dominated by multi-sector SMEs	1 from SACCI

Source: Table developed by authors from study data.

<sup>49</sup> Yadar (2008: p. 69).

<sup>50</sup> Kochanek (1995–1996: p. 530).

<sup>51</sup> Interview extract: 1.

**Table 3:** Related stakeholders under study.

<b>Government departments and agencies</b>	<b>MNCs and domestic companies</b>	<b>Consultancy companies and institutes</b>	<b>Partnerships</b>	<b>No. of interviewees</b>
BIRAC (India)	GSK (India)	PWC (India)	NEPAD (South Africa)	2 from BIRAC; 2 from NEPAD; 1 from PWC; 1 from GSK
DTI (South Africa)	Strand life sciences (India)	SERUM (India)		1 from DTI; 1 from SERUM; 3 from Strand life sciences
DST (South Africa)	Achira labs (India)			1 from Achira labs; 2 from DST
	Biocon (India)			1 from Biocon
	Pfiser (South Africa)			1 from Pfiser
	Africa bio (South Africa)			2 from Africa bio
	Litha (South Africa)			1 from Litha
	Johnson & Johnson (South Africa)			1 from Johnson & Johnson

Source: Table developed by authors from study data.

This fundamental division between British and Indian capital as well as caste-and-region-based social separations led to the emergence of a multiplicity of associations, representing industry in India.<sup>52</sup> In the decades since independence, and especially in the 1980s and in the 1990s, the roles and strategies of these associations have changed towards becoming less individualistic and more pluralistic. This means that they have ceased promoting patron-client relations. Instead, associations have become more open to businesses and industrial sectors. This corresponds to an accelerated process of political, economic and social change, taking place in India during that time. Specifically, at the level of politics, the electoral loss of the Congress Party in 1989 and the emerging pattern of coalition governments in the successive years have led to a competitive political environment that promotes public policy contributions by businesses and industrial sectors. At the level of economy and society, the New Economic Reforms in 1991 towards liberalization, export promotion, privatization and foreign direct investment (FDI) have encouraged the private industrial sector in areas such as health not only to innovate for achieving global competitiveness but also to collaborate with the government for achieving appropriate regulatory frameworks. This particular change has enabled health industry associations like OPPI to lobby the government in favor of policies such as strong IPRs. Given OPPI's representation

<sup>52</sup> Kochanek (1995–1996).

of research-based pharmaceuticals,<sup>53</sup> especially MNCs, the tightening of IPRs is considered to be a major incentive for producing innovative drugs and therapies. In OPPI's view, India can never become a "Drug Discovery and Pharma Innovation Hub" unless IPRs is genuinely respected.<sup>54</sup> Thus, one respondent from OPPI confirmed:

*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.<sup>55</sup>*

The 1990s liberalization era marked the end of India's long dispute about TRIPS, including its leading role during the GATT Uruguay Round talk in efforts against TRIPS which it and other countries, notably Brazil, Argentina and Mexico, argued would hurt their domestic pharmaceutical industries and restrict their access to affordable medicines. India's dropping of its opposition to TRIPS occurred with its signing of the Uruguay Round agreements in 1994 and its ascension to the WTO in 1995 which required India to reform its existing patent regime and come into TRIPS compliance. Based in part on its past argument against TRIPS and its stature as an emerging global player, India was able to negotiate a 10-year phase-in period (until January 2005) of the full patent protection on pharmaceuticals as required under TRIPS.<sup>56</sup>

India's liberalization has also enabled the emergence of new associations such as ABLE<sup>57</sup> with the objective to lobby for the Indian biopharma. This health industry currently includes more than 300 companies with total revenue more than US\$2.4 billion. Innovative products range from biosimilars and vaccines to bio-manufacturing and stem cells. As one respondent from ABLE explained:

*...there were a lot of lobbies for the chemical industries ... but there was none for the biotechnology and bio-companies.<sup>58</sup>*

It should be stressed that although health industry associations welcomed the 1990s liberalization in India, umbrella organizations such as FICCI opposed it fearing that increased competition from overseas would affect their members.

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**53** Here it should be said that OPPI only represents research-based MNCs in India and not the entire pharma sector. Other associations, including the Indian Drug Manufacturers Association (IDMA), represent domestic pharmaceutical companies and especially generics manufacturers.

**54** OPPI (2014).

**55** Interview extract: 2.

**56** Mueller (2007).

**57** ABLE (2012).

**58** Interview extract: 3.

This led to split in opinions about the right approach towards the New Economic Reforms. Other pro-liberal umbrella organizations such as CII criticized FICCI. Thus, as one respondent from CII clearly stated:

*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 organizations. 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.<sup>59</sup>*

This statement reflects the power conflict among umbrella organizations with regards to influencing government policy towards an outward-looking strategy of industrial innovation. Power conflict is crucial for understanding the process through which industrial elites compete for control over policies which serve their interests. It also reflects the fact that Indian business and industrial elites are far from being a unified community. Politically, the close identification of FICCI with the Indian National Congress has been considered to be unacceptable by more liberal industrialists.<sup>60</sup> In fact, the rise of CII is due to the conflict between individualistic and pluralist SBR. This conflict impacted Indian NSI in general and NSHI in particular. FICCI for instance has been preoccupied with keeping the cost of healthcare down. According to one respondent from FICCI:

*The single greatest importance...for India is to continue to offer the best and the cheapest medical care for the people of India. As you already know India offers the best and the cheapest medical care in the world in terms of the network, the cost of pharmaceutical products, and [the] cost of medical devices.<sup>61</sup>*

By contrast, CII has been preoccupied with fostering innovation and healthcare regardless of cost. According to one respondent from CII:

*We now have a healthcare ... team ... what is called the team for knowledge initiatives. [It] focuses squarely on innovation whether it is in biopharma it does not matter.<sup>62</sup>*

Given CII's general focus on India's NSI, its specific activities in the health sector are a small portion of what they do. However, CII fosters innovation in this sector by strengthening systemic linkages between key industrial and health innovation actors through, for example, summits (e.g., the annual pharma/life sciences/

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<sup>59</sup> Interview extract: 4.

<sup>60</sup> Kochanek (1995–1996).

<sup>61</sup> Interview extract: 5.

<sup>62</sup> Interview extract: 6.

biotech summit). It also initiates common standards in manufacturing health products and brings together academia and health industry and government.<sup>63</sup>

#### 4.1.2 The main activities of Indian associations

The activities of health industry-specific associations such as OPPI, IPA and ABLE are different from the activities of umbrella organizations such as CII and FICCI. The former act as interfaces of their members or as extensions of industry. This implies that they strictly represent the narrow interests of the health industry, and therefore, their activities range from trying to influence the government on health specific regulatory issues to diffusing knowledge and integrating different parts of the Indian NSHI. By contrast, the latter act as intermediaries between their members and government, meaning they do not strictly represent the narrow interests of one industry, and therefore, their activities range from creating framework conditions and incentives for innovation to setting up knowledge networks and creating innovation systems.

Specifically, in order to influence innovation policymaking, 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 different government departments. Upstream engagement seems to be an important lobbying practice for OPPI. This is because it brings the voice of a specific health industry to the ears of government. It is indicative that, only in 2013–2014, OPPI delegations met with policymakers and government authorities 65 times to discuss regulatory issues, ranging from clinical trials and quality of innovative medicines to patents and access to innovative health care.<sup>64</sup>

In addition to upstream engagement with government, OPPI also engages downstream with umbrella organizations. This is a new strategy that goes beyond submissions to government on issues such as IPRs. As one key respondent from OPPI revealed:

*I said every submission will not just say what we have to say but we will go and play an active role in all national chambers. So India has three national chambers: CII, FICCI and ASSOCHAM. I am co-chair of the ASSOCHAM committee on IPRs, I am co-chair at one of the sub-committees on IPRs at FICCI...*<sup>65</sup>

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<sup>63</sup> Herstatt, Tiwari, and Ernst (2008).

<sup>64</sup> OPPI (2014).

<sup>65</sup> Interview extract: 7.



This active engagement of OPPI downstream implies that power conflicts between associations often coexist with coalitions aimed at putting collective pressure to government for regulatory changes in favor of biopharmaceutical and clinical research companies. Let us take for example the area of clinical trials. OPPI works closely with several industry associations, including IPA, CII and FICCI, to press for clear criteria on grant waivers of Phase III clinical trials. Also this downstream engagement is intended to strengthen the regulatory position of association indirectly through negotiations of IPRs at multi-actor forums. Such forums include MNCs, generics companies, law firms, patent agents and NGOs.

It might be argued that all these public and private actors constitute India's NSHI. Health industry associations integrate industrial and social parts of that system as well as knowledge. The latter is diffused through collaboration and events such as conferences and meetings. As one respondent from OPPI said:

*Collaboration is anyway happening...we are talking to IPA, the Indian Pharmaceutical Alliance, IDMA...of course meetings and conferences are [platforms] which we jointly do...on ethics for example we did last month, with European experts coming and we invited Indian companies...and others participated.<sup>66</sup>*

One factor influencing integration is the mobility of elites and health experts from academia to industry and then to government and to associations. As one respondent from an MNC stressed, the need for mobility is crucial:

*You have to have people who move around, who are part of industry bodies, academic, government and I think their perspectives are very important.<sup>67</sup>*

Another factor influencing integration is the role of industry associations as brokers of public-private collaboration. For instance, associations such as ABLE and IPA act as brokers of collaboration between venture capitalists and entrepreneurs and policymakers. According to one key respondent from ABLE:

*Part of what ABLE did from its very early days was to organize what we call the Bioinvest conference where we actually bring investors and entrepreneurs together and public policy people and we typically organize these in Mumbai because that's where the investor company is.<sup>68</sup>*

India is a country with limited venture capital for start-ups in areas such as health related biotechnology. Therefore, the role of industry specific associations also

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<sup>66</sup> Interview extract: 8.

<sup>67</sup> Interview extract: 9.

<sup>68</sup> Interview extract: 10.

improves the funding conditions for new biotechnology firms. This is something that the traditional NSI approach to developing countries has ignored.<sup>69</sup> Specifically, it has ignored that in countries such as India, ABLE and other health industry associations fill in the gap of funding for early stages innovation by creating a pool of private equity or by bringing in the government.<sup>70</sup> The latter operates through public agencies such as BIRAC. As one key respondent from BIRAC confirmed:

*[Regarding] early funding, there is quite a lot...through BIRAC.<sup>71</sup>*

ABLE advises BIRAC on issues of funding for new technology start-ups, aiming to encourage more risk capital accumulation in India. Additionally, it organizes joint workshops on “Enterprise Building & Innovation” in to help biotech start-ups and SMEs building innovative capabilities. Certainly, the strategy of encouraging more risk capital accumulation for innovative start-ups has not been always successful. According to another respondent:

*...the government has been willing to put more capital ... but the government wants to manage it and then it's very difficult to take calculated risks because the auditors and the financial guidelines from government are much more conservative ....<sup>72</sup>*

In this stage, the role of specific industry associations such as ABLE is clear: they influence health innovation by proposing to the government different models of funding new technology start-ups. Our data confirms that, indeed “A well-organized private sector can make clear to the state where the priorities are for public investment and can monitor the quality of such investment.”<sup>73</sup> However, the identification of funding priorities for new technology start-ups is distinct from the activities of umbrella organizations such as CII and FICCI. As one respondent put it:

*ABLE was caring much more for young biotech companies and agencies like CII and FICCI have a little bit of bias towards the biggies....<sup>74</sup>*

Indeed it might be argued that umbrella organizations are concerned with broader industrial policy issues, and their aim is to influence the framework

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<sup>69</sup> Watkins et al. (2014).

<sup>70</sup> BioSpectrum (2013).

<sup>71</sup> Interview extract: 11.

<sup>72</sup> Interview extract: 12.

<sup>73</sup> Kathuria, Raj, and Sen (2013: p. 88).

<sup>74</sup> Interview extract: 13.

conditions within which innovation takes place. As one respondent from a consultancy company pointed out:

*CII and FICCI usually concentrate on big ticket policy items that are very high profile in nature, they closely connected with government, so they tend to hold annual summits with the government, policymakers and stakeholders both foreign and domestic and try to move the agenda on the key issues of the day: bureaucracy, regulatory, tax, strategy, basic industry issues.<sup>75</sup>*

It might be said that umbrella organizations in India have much more proactive and partnership approach to government than health industry specific associations. In fact, the latter have strongly reacted to government policies which failed to serve the narrow interests of their members. Since 2010, OPPI has released in the press hundreds of statements against government policies such as compulsory licensing, drug pricing, etc.<sup>76</sup> By contrast the former have co-operated with government in formulating and implementing some of these policies. The umbrella associations' partnership approach is increasingly evidence based. As a key respondent from FICCI stressed:

*They [umbrella organizations] started as lobby groups, plain and simple lobby groups. That continues in a semi-structured manner with...both awareness and evidence based, let us say advocacy so it is not pure lobbying any more. There is a lot of research that actually happens behind the original proposal of lobbying. That is a direct interface into the whole policy debate because there is fair amount of policy, resurgent policy debate.<sup>77</sup>*

This statement confirms the gradual involvement of umbrella organizations in India's governance of innovation. Such organizations have strong research teams and experts who collect data about their members' activities, including R&D and commercialization of new products. In addition, they employ consultancy firms to provide data and analyses of trends in particular sectors such as health. As one respondent from CII 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 program 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 program, this is our wish list and what can you do? Then they may call a meeting and that is the interaction that goes on.<sup>78</sup>*

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<sup>75</sup> Interview extract: 14.

<sup>76</sup> OPPI (2013).

<sup>77</sup> Interview extract: 15.

<sup>78</sup> Interview extract: 16.

This statement confirms Kochanek's early research finding that the success of umbrella organizations such as CII is due to the development of a close working relationship with key bureaucrats and an emphasis on common interests in economic development.<sup>79</sup>

#### 4.1.3 Indian associations as public actors of development

Our data suggests that despite the importance of both health industry associations and umbrella organizations in India's NSHI, only the latter can be considered to be public actors of development. This is because umbrella organizations such as FICCI and CII have clear developmental objectives. According to one respondent from FICCI:

*...the private sector is moving into the development space. The development space used to be purely a government run socialist concept... But I think now it is more or less obvious that industry bodies are also one more player in the development space.<sup>80</sup>*

Indeed umbrella organizations in India work closely with NGOs and international development agencies to promote innovation led growth and poverty reduction. For example, FICCI is part of the *Millennium Alliance* that aims at encouraging and scaling up innovations for development.<sup>81</sup> In the area of health, such innovations include: 3nethra – an integrated pre-screening ophthalmology device (a single portable pre-screening device that detects cataract, glaucoma and other problems) – and caremother – a mobile pregnancy care (a portable kit, mobile and web applications for high risk pregnancy identification, recording data and providing medical tests).<sup>82</sup> As one respondent from FICCI explained:

*...this initiative started in 2011 and USAID had certain sectors in mind, basic education, medicine and child health, clean energy, water sanitation, so these are the focus areas ... the Indian government graciously agreed to part with \$5 million ... and so USAID is contributing \$7.7 million ... we have a corpus now to which we give grants ...<sup>83</sup>.*

In contrast to umbrella organizations in India, health industry associations cannot be considered as public actors of development. Our data suggests despite the fact that they are key actors of the country's innovation system, they do not

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<sup>79</sup> Kochanek (1995–1996).

<sup>80</sup> Interview extract: 17.

<sup>81</sup> FICCI (2013).

<sup>82</sup> FICCI and USAID (2014).

<sup>83</sup> Interview extract: 18.

have common interest in development. As one respondent from a consultancy firm pointed out:

*[Health industry associations] succeed to create enough noise for the government to take notice of what they are doing ... The noise does impact the debate but may not steer it in [one] direction because of competing associations ...*<sup>84</sup>

In any case, our data clearly indicates that both umbrella organizations and health industry specific associations are important not only for the Indian innovation system but also for the political system. As one respondent put it:

*... all of them are very useful, they all have some roles to play ...the input of industry associations is hugely valued by the bureaucrats ... because for them at consensus time democracy works best when pieces of paper are given by the industry associations as opposed to a single large company.*<sup>85</sup>

Indeed, industry associations and umbrella organizations in India are part of the country's liberal pluralism. The latter lies behind a particular politics of development – i.e., the politics of bargaining and negotiation in areas such as health innovation. According to Manor (2001), the capacity to practice such politics prevents different economic interests and socio-cultural heterogeneities from creating political chaos.

## 4.2 South Africa

### 4.2.1 Context and historical background

South Africa, also one of the BRICS, made the transition from an apartheid state to a constitutional democratic state in 1994 and since then, has experienced exceptional economic growth 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 state and civil society. This relationship is characterized by vibrant interest groups and industry associations making claims on the state about two main issues: first, capability expansion through co-production of goods and services, and second, increased share of resource revenues for investment in innovation and development.<sup>86</sup>

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<sup>84</sup> Interview extract: 19.

<sup>85</sup> Interview extract: 20.

<sup>86</sup> Evans (2014); Heller (2011); Arrighi, Aschoff, and Scully (2010).

To understand the role of industry associations in South Africa, it is important to examine the early years of its transition to a democracy when the country moved towards a more pluralist approach to politics than corporatist. According to Lehman, “evidence strongly suggests that democratization...in South Africa since 1994, has weakened the corporatist hold of the state and has strengthened and expanded civil society.”<sup>87</sup> Corporatism is a concept associated with authoritarian regimes such as the apartheid state and describes a system of interest representation based on non-competing associations supervised and controlled by the state itself.<sup>88</sup> In contrast, neo-liberal pluralism describes a competitive market system of associations which form part of civil society – i.e., the realm in which members of society voluntarily create autonomous groups to advance their values and interests.<sup>89</sup> As Lehman points out, “the evolution of interest groups in South Africa has been interlined with neo-liberal economic policies, expansion of civil society and uneasy relationship with the state.”<sup>90</sup>

Indeed, this is clearly reflected in the case of two health industry specific associations: Pharmaceutical Industry Association of South Africa (PIASA) and Innovative Medicines South Africa (IMSA). As has been mentioned, in April 2013 these associations merged to form the Innovative Pharmaceutical Industry Association South Africa (IPASA), which currently represents MNCs that conduct their own R&D and excludes domestic pharmaceutical companies that have no Intellectual Property. Although the vision of IPASA appears to be better access to healthcare, the association is in uneasy negotiation with government over the latter’s policy plan to change the rules for medicine patents, which incorporates patent flexibilities<sup>91</sup> after the Doha Declaration<sup>92</sup> and recommends elimination of weak patents, promoting the production of generic drugs.<sup>93</sup> In response, IPASA appears to have embarked on an international campaign against full implementation of the government plan, lobbying for stronger intellectual property rights (IPR) regime on innovative medicines. 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 FDI into knowledge-based firms such as biopharmaceuticals.<sup>94</sup> As one respondent from IPASA put it:

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<sup>87</sup> Lehman (2008: p. 116).

<sup>88</sup> Nyang’oro (1986).

<sup>89</sup> Fioramonti (2005).

<sup>90</sup> Lehman (2008: p. 118).

<sup>91</sup> Correa and Matthews (2011).

<sup>92</sup> WTO (2001).

<sup>93</sup> DTI (2013).

<sup>94</sup> IPASA (2013).

*We currently have an environment where there is ... adequate respect for intellectual property rights. There is a policy on the table that proposes to change that. The policy itself is not clear enough to our minds, on where it's going or how it's going to be implemented ... There is a lot of misinformation going out there ...*<sup>95</sup>

In response to IPASA, the South African government insists that its policy plan is clearly not about weakening the TRIPS regime and the country's NSHI but about implementing TRIPS with all the necessary flexibilities for the sake of public good.<sup>96</sup> According to one policy maker from the Department of Trade and Industry (DTI):

*... the research industry overreacted ...[and] ... created unnecessary tension ...*<sup>97</sup>

But this tension mainly takes place between the Department of Health (DoH) and IPASA. Other government departments such as the DTI appear to be more sympathetic towards IPASA, trying to play the role of mediator between government and industry. For example as another policy maker from the DTI made clear:

*... the battle between government and big pharma is led by the health minister, not the DTI, so we try to mediate in one way, DTI is caught in the middle.*<sup>98</sup>

Although the tension between IPASA and government has not been resolved yet, it is important to point out that the uneasy relationship between health industry associations and government in South Africa has historical roots and goes back to the “Big Pharma vs Nelson Mandela” case in 1998.<sup>99</sup> Reacting against a new law that the Mandela government unveiled that would allow the country to import generic and cheap drugs to deal with health emergencies such as the HIV/AIDS crisis, the Pharmaceutical Manufacturers Association (PMA) and 39 MNCs filed a legal challenge against the government. While PMA agreed to drop their lawsuit after facing substantial international and domestic opposition in 2001, the trust between government and health industry associations had been already damaged. As one respondent from an MNC pointed out:

*... pre-1994 I think the industry was more in an advisory role, although perhaps not with lobbying focus, access to government ministries was quite possible. What changed it completely for the industry was the court case of 1998–2004 which was all about weakening intellectual*

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<sup>95</sup> Interview extract: 21.

<sup>96</sup> *The Economist*, 27 January 2014, “The New Drug War Continued.”

<sup>97</sup> Interview extract: 22.

<sup>98</sup> Interview extract: 23.

<sup>99</sup> *The Guardian*, 18 April 2001, “Firms Split Over Deal in Cheap Drugs Lawsuit.”

*property and so created a sense that we [the industry] were against the government. So from that time onward, whenever you went into the halls of government, they [the government] would see you as 'you are that industry that took us to court'; so that created such animosity between the department of health, the relationship has never really been constructive.<sup>100</sup>*

This statement confirms that, in South Africa, state business relations (SBR) in the area of health innovation are fragile and therefore, lack the essential characteristics of effectiveness. According to Cali and Sen such characteristics include:

*(i) transparency: whether there is a flow of accurate and reliable information, both ways, between business and government, and from representatives of business to their own members; (ii) reciprocity: whether there is capacity and autonomy of state actions to secure improved performance in return for subsidies; (iii) credibility: whether the state command credibility of the private sector, and whether capitalists are able to believe what state actors say; and (iv) whether there is mutual trust between the state and the business sector...<sup>101</sup>*

Clearly, South African SBR in the area of health innovation is neither transparent and reciprocal nor credible and mutually trusted. This ineffective SBR seems to deeply concern several MNCs in South Africa as a result of their progressive inability to influence the government. Instead, other civil society groups have entered the pluralist arena, becoming successful in shifting the focus of policy and practice away from innovative drug patents and towards expanding the import of cheap drugs from other markets such as India. Therefore, MNCs argue that biopharmaceutical innovation in South Africa is being undermined. According to one respondent from an MNC:

*The big drive now which is happening, which is actually very concerning, you can see now our [industry] lobbying efforts have been very ineffectual and the winners in lobbying have been the activists.<sup>102</sup>*

Although this statement cannot be fully triangulated, it reveals the strong competition between health industry specific associations and other civil society actors for influencing the values and direction of health innovation in South Africa. It also confirms the emerging neo-liberal pluralism in the country that is highly competitive and eventually leads to winners and losers of power over influencing regulation and governance of health innovation.

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**100** Interview extract: 24.

**101** Cali and Sen (2011: p. 1543).

**102** Interview extract: 25.



#### 4.2.2 Main activities of South African associations

Like in the case of India, health industry associations in South Africa such as IPASA and the National Association of Pharmaceutical Manufacturers (NAPM) pursue different activities from umbrella organizations such as the South African Chambers of Commerce and Industry (SACCI). The former are extensions of industry and tend to focus on regulatory issues concerning pricing policy, marketing guidelines and drug registration; dealing with these issues serves the narrow interests of their members. By contrast, the latter are intermediaries and thus tend to focus on wider innovation issues and legislation; addressing such wider issues serves the broad interests of different industrial sectors.

Specifically, in order to influence government policy, IPASA collaborates with NAPM and other actors of health innovation, advancing demands for reduction of regulatory timelines, advising on pricing factors and pressing for better framework conditions of innovation. As a key respondent from IPASA confirmed:

*... there is a lot of collaboration in industry; we have IPASA, we have NAPM ... which is mainly generic ... we have SAMED ... and there is PHARMISA which is the South African companies. We collaborate with them on a thing called the PTG, which deals more with pricing of medicines policy ... we co-operate with them on regulatory issues ....*<sup>103</sup>

Comparing to India, it seems the trend in South Africa is more downstream than upstream engagement. This can be explained by the fragile SBR in the area of health innovation. By engaging downstream, health industry specific associations appear to have a better chance to form a strong coalition vis-à-vis government policy. This does not necessarily imply lack of upstream engagement. On the contrary, as another respondent from IPASA stressed:

*With government we've got three key departments: health, trade and industry, and science and technology. We will watch their policy-making process, we will engage with them at Parliamentary level ... so if there is a policy issue we will request an opportunity to present our position to the Portfolio Committee who will discuss it. We have reasonable access to the chairs of those committees on a lot of issues ... we are the gatekeepers, we will say 'whoops here comes the government gazette, this is how we understand its impact, come sit.'*<sup>104</sup>

Certainly, one of the problems in upstream engagement is the fragmentation between government departments. Our data suggest that the Departments of Health (DoH), Trade and Industry (DTI) and Science and Technology (DST) have

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<sup>103</sup> Interview extract: 26.

<sup>104</sup> Interview extract: 27.

different approaches to health innovation. For example, the DoH is more hostile towards patents of innovative medicines and vaccines than the other departments such as DST. Therefore, the South African IP policy remains unclear. As one respondent from DTI said:

*On the one hand the head of [health] department believes that patents are a major obstacle to access of modern drugs. On the other hand you have the industry which is quite in trouble; the research based industry is out of 1 trillion dollar market ....*<sup>105</sup>

This statement indicates that DTI takes on board the health industry's concerns about IP, especially that of incentivizing investment in innovative medicines (e.g., a new family of anti-inflammatory drugs). One reason might be that members of the department maintain close contact with associations such as IPASA and NAPM. As another respondent from DTI stressed:

*... [members of DTI attend events organized by industry associations] – for example, two weeks ago I attended a conference with all medical schemes and insurers, it is interface between medical insurance clusters, so we are invited, we attend ....*<sup>106</sup>

Despite this close relationship, DTI also interacts with individual companies. As the same respondent from DTI revealed:

*...in most cases due to sensitivities such as new products and investment, I would say that more often we deal with individual companies.*<sup>107</sup>

Our data suggest that the reason why policymakers often prefer to interact with individual companies is because of the strong competition among health industry associations. Such competition prevents them from speaking with one voice to the government.

The problem of fragmentation is less obvious in the relations between government and umbrella associations. Like in India, umbrella associations in South Africa are concerned with broader innovation policy issues that affect many different industrial sectors. According to a key respondent from SACCI:

*The process is that in South Africa the constitution and judicial fair process requires that stakeholders are presented with the opportunity to comment on new legislation and policy, usually it is a period of 30 days. So we would provide a fair comment, send it to our members, get mandate and send it to government.*<sup>108</sup>

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**105** Interview extract: 28.

**106** Interview extract: 29.

**107** Interview extract: 30.

**108** Interview extract: 31.

The South African constitution enables umbrella organizations such as SACCI to work in partnership with the government on some innovation policy measures. This is not the case with health industry specific associations such as IPASA. The latter appears to be more reactive to the government while the former appears to be more proactive. As one respondent from SACCI admits:

*...we do have a very good relationship with government, all things considered. We regularly house cabinet members at our breakfast events and this provides an opportunity for our members to first-hand meet the minister and I think it's also a good thing to be able to see the person....<sup>109</sup>*

This statement confirms the high level of interaction between umbrella associations and the South African government. For SACCI in particular, interaction is the guiding principle of its main activities. Like in the case of India, this interaction is evidence based – i.e., umbrella associations such as SACCI provide evidence and information to the government for certain types of health innovation policy. As one respondent from DTI said:

*For example, when it comes to National Health Insurance they provide information on the health and economic outcomes, the pros and cons. The National Health Insurance is important for them, the reason being that it could reduce the role of research based companies in the pharmaceutical sector; the government will be buying generics rather than innovative products ....<sup>110</sup>*

But interaction also takes place between umbrella organizations and health industry specific associations and corporate groups. This is because collective action appears to be more successful with the engagement of different actors of the NSHI. One respondent from SACCI describes this downstream engagement as follows:

*... we are fortunate that we can engage directly with high-level senior members of those corporates but we also obviously engage with IPASA, we've had meetings together ... in terms of lobbying what we have realized is that it's good to have an industry body but it also adds wait to an argument if a corporate is there ....<sup>111</sup>*

Through these multiple interactions, knowledge and information are diffused to South Africa's NSHI. Key actors of the system such as biopharmaceutical compa-

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**109** Interview extract: 32.

**110** Interview extract: 33.

**111** Interview extract: 34.

nies use these knowledge and information for improving their innovative capabilities. According to one respondent from a company:

*If you are not part of association you miss out a lot of information.*<sup>112</sup>

### 4.2.3 South African associations as public actors of development

Our data suggests that, despite the crucial role both health industry and umbrella associations play in South Africa's NSHI, only the latter can be considered to be public actors of development. This is for the same reasons discussed in the case of India. Umbrella associations in South Africa such as SACCI have broad development objectives that tend to go beyond innovation, whereas health industry specific associations such as IPAS, have very narrow objectives that tend to focus on interests of their member companies. As one respondent from SACCI put it:

*I think the subtext to every single comment we make to government is about job creation and economic growth. So we are not a developmental financial institution, we do not give money ... but we try to steer policy towards a trend that is more conducive to economic growth.*<sup>113</sup>

Although there is no evidence that umbrella organizations in South Africa work closely with NGOs to promote development, it is clear that these associations are concerned with improving framework conditions for both innovation and development. For example SACCI focuses on the illicit market for pharmaceutical products suggesting specific policies and regulations:

*South Africa does have very large illicit market for these products because it's a developing economy, it's got links with organized crime, it's really scary. So over-taxing or over-regulating these industries is not going to increase consumption, it's going to make it more dangerous to consume because there are going to be more illicit products.*<sup>114</sup>

SACCI's specific policy suggestions and regulations aim at putting in place better market institutions and reducing the interventionist role of government. This implies neo-liberal politics of development that is consistent with the country's emerging pluralism.

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<sup>112</sup> Interview extract: 35.

<sup>113</sup> Interview extract: 36.

<sup>114</sup> Interview extract: 37.

## 5 Discussion

### 5.1 Emerging pluralism

Our case studies suggest that, in both India and South Africa, health industry associations are formed as public actors, which, on the one hand, provide their members with industry-specific public goods (ISPGs) and on the other, influence health innovation and the politics of development. To do so, these associations develop a range of capabilities, including representation in government, international co-operation, intermediation, knowledge diffusion, policy involvement and collaboration. If health industry associations did not exist, there would be no collective action of pharmaceutical companies and related stakeholders to challenge and/or improve government regulations for health innovation. A strong national system of health innovation (NHSI) presupposes interaction and collaboration between public and private actors. Health industry associations can effectively play the role of intermediaries, bringing these different actors together and diffusing knowledge and innovation.

The economic and political context within which the activities of health industry associations take place seems to be that of “emerging pluralism” – a dynamic context of bargaining between competing (public and private) interests and values.<sup>115</sup> In the case of India, such context is the result of historical evolution of liberal procedures of the parliamentary democracy. Despite the fact that the state remains a strong authority, it allows a democratic process based on the interaction of competing associations and interest groups.<sup>116</sup> In the case of South Africa, emerging pluralism is the result of the evolution of democratization that was tied to economic and political liberalization.<sup>117</sup> Competing interests and values are advocated by associations of civil society.<sup>118</sup> These public actors exercise power over the politics of development and systems of innovation in developing countries. The degree of such power seems to depend on the degree of democratic accountability of political systems and innovation frameworks. As Mahoney points out, policymakers that are accountable to the public appear to be more responsive to associations than policymakers that are not accountable.<sup>119</sup>

It might be argued that in both India and South Africa accountability and pluralism historically emerged in the 1990s. In India, the economic and political reforms

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**115** Dahl (1989).

**116** Muñoz-Fraticelli (2014).

**117** Leftwich (2006).

**118** White (1993).

**119** Mahoney (2007).

which took place in that decade created the space for health industry associations and other civil society organizations to negotiate power and lobby governments for pro-innovation regulation and governance.<sup>120</sup> To put it another way, pressure was put on the 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 liberalization. As Basile and Harris-White point out, "the era of liberalization 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."<sup>121</sup> One critique of this emerging liberal politics is that it leads India towards a chaotic process of industrial policy. Various business interests compete for influencing the political process. The result of competition is that certain power dynamics take 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. SBR appear to be crucial for developing and implementing the South African innovation system, increasing innovative capabilities in biopharmaceuticals. Public action is always purposive collective action.<sup>122</sup> Therefore, health 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 health industry associations and umbrella organizations 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 and for helping them to co-ordinate changes in their challenging environment.<sup>123</sup>

## 5.2 Upstream engagement

Our data confirm that, despite their different focus, health industry associations in the developmental contexts of India and South Africa play dual insti-

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<sup>120</sup> Corbridge (2009).

<sup>121</sup> Basile and Harris-White (2000: p. 11).

<sup>122</sup> Mackintosh (1992).

<sup>123</sup> Teece and Pisano (1994).

tutional roles. On the one hand, they engage upstream to lobby their respective governments 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 health industry associations to get their views on the policy agenda, influencing the executive part of government.<sup>124</sup> Indeed, as Cavazos and Szyliowicz confirm,

*“Associations will often work to set the agenda while simultaneously aiming to build awareness, influence policymakers and gain favorable legal decisions. They will finally strive to ensure that their successes are not dissipated in the implementation stage and that favorable 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.”*<sup>125</sup>

In developmental contexts, such activities appear to strengthen institutional development and positively affect industry conditions. The threat 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, umbrella organizations in developmental contexts constitute policy instruments of governments. This goes beyond corporatism and towards co-regulation or joined-up governance.<sup>126</sup> For instance, as our case studies suggest, CII, FICCI and SACCI develop partnerships and co-regulate with governments, ensuring that their members would implement policies. Implementation of co-regulated policies and practices is a membership condition for some pharmaceutical associations in developing countries, and therefore, governments do not need to spend more resources in order to enforce implementation. Health industry associations and umbrella organizations also provide policy input to governments for negotiating international agreements such as TRIPS.<sup>127</sup>

### 5.3 Downstream engagement

Health industry associations and umbrella organizations not only engage upstream, working closely with the state and governments to promote specific regulations and provision of ISPGs, but also engage downstream, developing

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<sup>124</sup> Nelson (2000).

<sup>125</sup> Cavazos and Szyliowicz (2011: p. 476).

<sup>126</sup> Cawson (1982).

<sup>127</sup> Athreye and Chaturvedi (2007).

partnerships and/or coalitions with other associations and businesses for the achievement of common objectives. According to Cavazos and Szyliowicz,

*Coalition building is particularly effective in many settings since it is characterized 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.<sup>128</sup>*

Especially in South Africa but also in India, our data suggest that such coalitions are strong, indicating common perspectives across different industrial sectors. Umbrella organizations, such as CII, work together with OPPI to improve the framework conditions for knowledge diffusion and technological innovation.

Coalitions and partnerships transcend national borders – i.e., health industry associations of developing countries increasingly develop coalitions with health industry associations and other lobbying groups of developed countries but also global public actors like the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). These coalitions not only put pressure on global institutions such as the World Trade Organization (WTO) with regards to global health governance but also to diffuse 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 health industry associations and umbrella organizations in health innovation and the politics of development, focusing specifically on India and South Africa. The argument has been that such associations constitute public actors which not only diffuse knowledge to innovation systems but also engage upstream in uneasy relationships with governments and downstream in coalitions with other associations. Health industry associations and umbrella organizations in India and South African operate in an economic and political context of emerging pluralism, which not only enables them to collaborate for advancing common claims to government but also for becoming government partners for innovation and development. This dual role of health industry associations and umbrella organizations makes them less neutral politically but more effective institutionally. Given that

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<sup>128</sup> Cavazos and Szyliowicz (2011: p. 475).



innovation and development institutions in India and South Africa are often weak and/or fragmented, market processes and government interventions are not always sufficient to resolve these problems. In a number of respects, industry associations and the government co-develop policies and regulations which impact health innovation. Therefore, their innovative and political role should be seriously taken into account in the healthcare sector. Certainly, further research is needed to unpack the precise power relations and the rent seeking dynamics which influence the upstream and downstream engagements of industry associations in developing countries. Our empirical study has only indicated the uneasiness of such engagements. Future research ought to go beyond that and towards determining sources and uses of collective power within innovation systems of emerging pluralist countries.

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