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Industry Associations and the Changing Politics of Making Medicines in South Africa

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Introduction

The making and delivery of new medicines is not only a process of science and technology, of production and marketing, but also a process that is inherently political. As such, the relational and political interactions between industry and government are key to shaping regulatory environments that either promote or constrain an industry's ability to collectively learn, innovate and grow (Malerba, 2002). Often critical to the governing of these relations over time are intermediary actors such as industry associations and various advocacy groups that through processes of conflict, negotiation and collaboration promote knowledge exchange and institutional capacity building. In developing and emerging countries, such intermediaries are likely to play a particularly prominent role in filling institutional knowledge gaps towards shaping regulation and subsequent industry development (Kshetri and Dholakia, 2009). Moreover, these interactions between industry and government can be particularly complex and often contentious when government views an industry as potentially contributing to the public good, as in the case of the pharmaceutical industry and its role in the provision of health care. In such cases, it can be suggested that the strategies employed by industry associations over time will need to address the needs of the government and the civil society it negotiates with in order to effectively advance the interests of the industry it represents.

This chapter builds on these notions by analysing the changing role of biopharmaceutical industry associations and related umbrella organizations in South Africa since the 1960s when the sector's first industry

association was formed. More specifically, we examine the ways in which the changing political context and institutional interplay have shaped a South African industry-government relational trajectory that is historically uneven and reactively contentious. In this case, respective pharmaceutical associations have shifted gradually away from pure, narrowly aimed lobbying tactics to greater cooperation with government and civil society on a host of policy-related issues, from health innovation to national goals of development.

Our analysis considers developments during three main periods through which the South African biopharmaceutical industry has evolved: (1) a period of pre-liberalization; (2) a period of expanding pluralism; and (3) a period characterized by increasing partnership. While the activities of industry associations reside primarily in the second and third periods, a discussion of the first period is deemed essential in understanding the unfolding of industry-government relations in subsequent and more recent periods. Findings indicate that two decades of both increasing pluralism and globalization have created tensions amidst regulatory uncertainties between government and the pharmaceutical industry regarding access to medicines on the one hand and strong intellectual property rights (IPRs) on the other. We suggest that such uncertainties can be reduced through improving interaction between biopharmaceutical industry associations, government and civil society organizations (CSOs). This can result in more legitimate and cumulative platforms for partnering on a number of regulatory issues and broader, more holistic developmental aims.

We begin this chapter by positioning industry associations as intermediaries within a broader policy subsystem and clarifying their importance in the developing and emerging country context. We then consider the activities of industry associations within wider government-industry growth and development coalitions, presenting both the challenges and opportunities towards potentially collaborative yet inherently political relations. We follow this with a brief overview of the South African case and the approach and methodology employed in our analysis. Next, we consider the importance of historically embedded relational dynamics between government and the pharmaceutical industry in South Africa that are punctuated by periods of regulatory uncertainty, mostly involving intellectual property regimes that either reinforce or alter existing relational trajectories. We underpin our analysis with evidence from case studies on four industry associations engaged in the South African pharmaceutical industry.¹ These case studies include interviews with senior managers, biopharmaceutical and other industry association

presidents and government policy makers in relevant departments. These findings, along with data collected through various secondary sources, lend insights into the current political strategies of biopharmaceutical industry associations and the possibilities of more development-oriented government-industry coalitions going forward.

Industry associations and the policy subsystem

We define industry associations as industry specific member-based organizations that actively lobby and negotiate with government on their members' behalf to shape government policy and regulation. Included in this are business umbrella groups such as chambers of commerce who represent the interests of a number of industries and sectors, and are engaged in broad industry coalition building. These organizations are part of what Sabatier (1991) describes as the 'policy subsystem' comprised of intermediary bodies regularly involved – through a variety of aggregation processes – in the shaping of policy within their specific domain of interest (Jenkins-Smith and Sabatier, 1994). For developing and emerging countries, this subsystem is bound to be particularly important where given institutional capacities for innovation and industry growth will often be lacking (Frankel, 2006), and where their potential development will be the result of politically contested relations between government, industry and civil society. Furthermore, these are likely to involve considerable negotiation between local and global interests (e.g. international bodies and multinational companies [MNCs]). In this context, industry associations will likely play a leading role in bridging institutional knowledge gaps between government and industry, and between the local and the global (Kshetri and Dholakia, 2009).

To advocate their members' interests successfully, industry associations will generally need to engage in and perform the following activities and functions. First, industry associations will employ far-reaching knowledge and information gathering and dissemination activities that target government, the broader industry community and the public. Second, industry associations will develop and maintain working relations with key individuals and ministries in government, often using 'elite' members and officials to lead outreach and lobbying efforts (Kshetri and Dholakia, 2009). Third, industry associations must be capable of building widespread industry coalitions for engaging with government. Otherwise, industry fragmentation can result in an ineffective industry voice; this can lead to government-industry tensions during times of regulatory uncertainty and less-than-optimal policy outcomes. Finally,

industry associations will need to function as 'veto players' which influence politics of development and therefore governing structures of innovation capabilities (Tsebelis, 2002). In the context of developing countries, it is increasingly acknowledged that the political creation of successful institutions of innovation happens under significant pressure from industry associations (Doner and Sheneider, 2000).

Despite their potential contribution to development, negative connotations are often ascribed to industry associations and their activities, as they have been viewed as controversial actors of innovation and development. For instance, as early as the 18th century, Adam Smith, in his *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. More recently, industry associations have been viewed as special interest groups and/or elitist organizations that pursue narrow rents for a limited number of members at the expense of the wider sector and economy, discouraging competition and thus curtailing collective innovation within an industry (see Olson, 1982; Schmitter and Streeck, 1999). This aligns with ideas concerning corporatism where national economic policy is formed through closely coordinated collaboration between government, industry and labour, either imposed by the government (state corporatism) or formed voluntarily (neo-corporatism) (see Schmitter, 1974; Cawson, 1986). Examples of these might be apartheid-era South Africa and contemporary Sweden, respectively (Thomas, 2004). Schmitter (1974) was concerned with what he coined 'societal corporatism', where a small number of interest organizations are able to monopolize the policy subsystem, competitively eliminating other interest groups and essentially forcing the government to enter into collaborative relations with industry due to political necessity (Maree, 1993). In some cases, some form of societal corporatism may be beneficial, allowing for more rapid development of national capacities during times of necessity or crisis. The obvious downside of societal corporatism is that the state can become beholden to a few key interest groups, for example a small group of domestic conglomerates or a select number of foreign companies. In this way it is thought that industry associations, in certain political contexts, can even threaten democracy (Cawson, 1982).

State-industry relations and coalitions towards development

While industry associations may influence the shaping of government-industry relations, the strategies they employ and the subsequent extent

to which government and industry work together may be determined more by long-standing and embedded relational dynamics between the two. Relations between government and industry are often referred to as coalitions, in that some degree of co-dependence and thus cooperation between government and industry is not only inevitable but necessary. In the context of developing countries, relations between government and industry may be characterized as 'growth coalitions', ranging from 'weak growth coalitions' where there is at least a minimal recognition that 'business needs the support of government to make profits; governments need to share in these profits to finance government and politics' (Moore and Schmitz, 2008: 1), to 'strong growth coalitions' where government and industry engage in active cooperation towards the goal of policies that both parties expect to foster investment and increase in productivity (Brautigam et al., 2002). According to Schneider and Maxfield (1997), strong growth coalitions require government and industry to share information and to have a high degree of 'reciprocity, trust, and credibility' towards one another. However, this does not change the fact that growth coalitions presuppose bargaining or compromises between industrial and political elites and CSOs. Khan (1995, 2000) refers to such coalitions as forms of political settlements – the balance-of-power among contending elites, CSOs and social groups. Political settlements are based on a common understanding of how narrow elitist interests can be served through policies of innovation and development.

Since the 1980s, a main focus of political-industrial settlements or government-industry relations for many developing countries, including South Africa, has been the implementation of neo-liberal economic policies. Cornerstones of this policy approach include currency stabilization, denationalization of industry, trade liberalization through the lowering of trade barriers, providing incentives for exporters and reducing favourable treatment of domestic firms, as well as the cutting of deficits for decreasing inflation and lowering interest rates – all aimed at spurring domestic innovation and growth in conjunction with increased foreign direct investment. Results of such neo-liberal-focussed growth coalitions have been mixed, with many developing countries experiencing sharp yet isolated increases in growth and wealth production amidst continued widespread poverty. For developing countries, therefore, it has been argued that government-industry growth coalitions need to evolve to a more development-oriented model that focuses on poverty alleviation over an extended period of time (Brautigam, 1997, 2009; Handley, 2008). Seekings and Nattrass (2011: 339) argue, however, that

development coalitions necessitate ‘much deeper deliberation and negotiation than a growth coalition: the objective is not only to agree on the mix of public sticks and carrots that serve to promote economic growth, but to agree on a mix that promotes a particular pattern of growth’, one that is focussed on the needs and welfare of the poor. For industry and the associations that negotiate with government on industry’s behalf, such a move would require a considerable shift away from pure lobbying to greater partnering with government.

The global pharmaceutical industry and the case of South Africa

The global biopharmaceutical industry is comprised of a relatively small number of large research-oriented MNCs based mainly in the developed North and a large number of both small and large companies that manufacture generic medicines both in the developed North but most prominently and increasingly so in the developing South (see Chapter 6). Most generics manufacturers operate as independent companies while others are subsidiaries of large MNCs. The research-based MNCs make generally large profits through the global sale of patented blockbuster drugs which are more expensive than generics and are at times priced out of the reach of poor patients. The research-based MNCs insist that the high prices for the medicines they sell and the profits they garner are necessary for covering the costs of marketing and continued R&D activities. But the inability of many to pay these prices, including the governments of developing countries, and the increasing expiration of many patented medicines have facilitated the tremendous growth of the generics industry which has substantially lowered the price for a number of essential medicines, including anti-malarial, and anti-retroviral drugs, among many others, some experiencing a 50–90% reduction in price, thus considerably increasing access to these medicines. The growth of the generic medicines industry and its impact on research-based MNCs have created considerable fragmentation and conflict within the pharmaceutical industry and between the pharmaceutical industry and the governments of emerging countries such as South Africa.

South Africa’s economic growth for the last few years has averaged 2–3% and it slowed down to 2.0% in 2014. However, as the second-largest African economy after Nigeria the country exerts strong economic and political influence on the African continent. The country made the transition from an apartheid state to a constitutional democratic state in 1994. Since then, South Africa has experienced considerable economic

growth, but also increased inequality and extreme poverty in certain sections of the population. In the area of biopharmaceuticals, the country has emerged as the industry forerunner in Africa with a significant presence of both domestic manufacturers and MNCs, although the domestic manufacturing industry is relatively small, with up to 65% of the country's pharmaceuticals still being imported (IPASA, 2013). Furthermore, its private market, worth US\$2.8 billion in 2012, is relatively small and constitutes less than 1% of the market globally. In 2011, two leading pharmaceutical companies in South Africa were domestically based MNCs, Aspen Pharmacare and Adcock Ingram; domestic companies import up to 90% of active pharmaceutical ingredients from other countries, including India and China. Meanwhile, historically, and presently, the country has had a number of active biopharmaceutical industry associations, making it an important case study for investigating the realities of pharmaceutical production in Africa and the role of industry associations in it.

With respect to industry associations, companies in this sector are members of different associations depending on the segment of the market that they occupy. Most foreign MNCs are members of the newly formed Innovative Pharmaceutical Association South Africa (IPASA), which emerged from a merger between two former associations, Innovative Medicines South Africa (IMSA), for research-based/innovator MNCs; and Pharmaceutical Industry Association of South Africa (PIASA), whose membership included both innovator and generics companies. The new association, IPASA currently represents 24 innovative pharma companies dedicated to producing or importing 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 intellectual property (IP) are excluded from the new association. Only IP holders, for example MNCs with innovator products, can become members of IPASA. In addition to IPASA, there is also the National Association of Pharmaceutical Manufacturers (NAPM), Pharmaceuticals Made in South Africa (PHARMISA), Self-Medication Manufacturers Association of South Africa (SMASA) and National Association of Pharmaceutical Wholesalers (NAPW), among others. They also all belong to the Pharmaceutical Task Group (PTG), a broad coalition involving IPASA, NAPM, PHARMISA and SMASA. The PTG deals with the government on issues of mutual concern such as pricing, regulation and national health insurance. For example, the PTG has retained an advocate to represent the pharmaceutical industry in the Competition Commission enquiry into high health care prices. That

being said, many of these associations and member companies are also members of the leading chambers of commerce, CHAMSA and SACCI, and connect with one another through these platforms. This current status of industry has evolved through two main periods: pre-liberalization and the post-apartheid.

Pre-liberalization era

While disagreements over the past two decades on particular regulatory issues have at times stymied relations between the South African pharmaceutical industry and the South African government, tensions between the two are very much rooted in a long history of tense and generally non-negotiable relations between the South African government and the South African business elites, which have carried over into more recent periods from the apartheid era. As Seekings and Nattrass (2011: 343–44) explain,

Indeed, relations between state and business in South Africa throughout the 20th century were framed by the coexistence of a strong state and powerful corporate capital. The state enjoyed considerable political autonomy from capital, but remained dependent on capital for continued economic growth. The outcome was often tense relationships, as the state sought to push and bully capital into subordinate co-operation, whilst avoiding genuine deliberation, and being careful not to undermine white prosperity.

As such, during the apartheid era, the South African government was intent on maintaining and enriching the white minority through ever increasing control and exploitation of the black majority. This necessitated a command-oriented state, the brutal subjugation of blacks and the complicity of white-owned industry which was dominated by a small number of large state-supported conglomerates all linked in some manner to the South African gold-mining industry. Offering considerable trade protection (much of this induced through international boycott) and ensuring low-wage black labour, the South African government expected industry to operate within certain constraints and to be ‘subservient, as long as it was dependent on state patronage’ (Seekings and Nattrass, 2011: 344); this resulted in a state-industry relationship that was generally reactive yet ultimately accommodating in terms of industry response, and largely devoid of negotiated compromise.

With an economy centred on mining and energy extraction, and stagnated by the apartheid system and resulting sanctions and boycotts, the

South African government lacked the ability and capacity to either invest in a broad-based science and technology infrastructure (e.g. weak university R&D) or facilitate the growth of technology-based industries (the exception being defence). A strong domestic pharmaceutical industry was never really established in South Africa during this period. The need for medicines, however, meant that large research-based pharmaceutical MNCs continued to sell and distribute medicines in South Africa, with some operating manufacturing facilities in the country. That being said, two pharmaceutical companies, Sterling Winthrop and Merck, divested their interests in South Africa and left the country due to the boycott. A few domestic generics-based pharmaceutical companies such as Adcock Ingram were able to successfully operate under the constraints of apartheid, but their growth and proliferation would not really occur until after apartheid's end. During this period, two main biopharmaceutical industry associations were established. The first was the South African Pharmaceutical Manufacturers Association (PMA), established in 1967, and the second was the National Association of Pharmaceutical Manufacturers (NAPM), established in 1977. The membership of the PMA was a mix of domestic and foreign-owned pharmaceutical companies, but the MNCs were more dominant given their market strength; members of NAPM, by contrast, were almost solely domestic manufacturers of generics. Both associations used to work closely with government and/or play advisory roles in policy areas such as health and drug manufacturing. This was consistent with the corporatist state-industry relations of the apartheid era.

Post-apartheid South Africa

South Africa's transition to democracy in 1994 led to weakening of the corporatist hold of the state and strengthening of the civil society (Lehman, 2008). This does not imply that a pluralist approach to state-industry relationships prevailed. Rather, pluralism and corporatism seem to coexist in post-apartheid South Africa. The relationships between industry associations and state appear to be co-operative; governments tend to view the business elites as a key player in pro-market liberal reforms. Indeed, as Seeking and Nattrass (2011: 339) point out, 'Capitalism not only survived the transition from apartheid to democracy, but high profit rates suggest that capitalism continues to flourish in the post-apartheid environment'. This is precisely the reason why South Africa, despite its exceptional economic performance, experiences increased inequality and extreme poverty in certain sections of population, namely the black majority. The co-operative state-industry

relations in the post-apartheid era failed to form a strong 'growth coalition' that could also deliver development. Therefore, within the governing party – the African National Congress (ANC) – the new political elite(s) developed distrust against the business elite(s). The ANC adopted pro-market policies with respect to the global economy without necessarily having a pro-business or pro-industry attitude. According to Seeking and Nattrass (2011: 344), 'In the early 1990s, two views of businesses coexisted within the ANC. On the one hand, business was seen to have been one of the pillars of apartheid, exploitative of workers and abusive of consumers. On the other, there was a growing appreciation of the overall weakness of South African capitalism, in particular its inefficiencies stemming from chronic protection against foreign competition and over-concentration'. The first view clearly supported regulation of employment relations and protection of black businesses. The second view supported trade liberalization and industrial policy. As Seeking and Nattrass (2011) observe, both views entailed a commandist approach to business and industry without so much negotiation.

In this post-apartheid mix of corporatism and pluralism, large pharmaceutical companies began to re-establish themselves in South Africa, insisting on strong protection of patented drugs through TRIPS. On the other hand, CSOs such as non-governmental organizations (NGOs) and advocacy groups began to formally participate in the policy-making process (Lehman, 2008). In 1994 there were more than 50,000 NGOs in South Africa, most of them pursuing development objectives (Fioramonti, 2005). In the post-apartheid era, the state inherited a strong regulatory capacity (*ibid*) and relied on it to protect public health from the spread of diseases such as HIV/AIDS through the poorest sections of population. According to Seekings and Nattrass (2011: 353), 'Its interventions in the private sector were programmatic rather than targeted in that the state legislated frameworks for change...and then endeavoured – with mixed success – to ensure that private sector complied with the statutory requirement'.

One well-known intervention was the government's 1997 Medicines and Related Substances Control Act that would allow South Africa to import and manufacture cheaper generic HIV drugs. This Act prompted 39 big pharmaceutical companies (mainly MNCs) to file through PMA a patent right lawsuit against the South African government – the so-called Big Pharma v Nelson Mandela case. In response, CSOs and activists accused PMA of violations of the human right to health by making essential medicines unaffordable and called the international

community to protect developing countries against big pharmaceutical companies (Wolff, 2012). Although in 2001 PMA agreed to drop the lawsuit as a result of the growing opposition, it was too late. The PMA suffered an international public relations disaster with three MNCs, GlaxoSmithKline, Merck and Bristol-Meyers Squibb, breaking ranks with 36 other companies and pushing hard for a settlement that would stave off increasing damage (*The Guardian*, 2001). Eventually, these 36 companies agreed to go along with the lawsuit withdrawal, but PMA dissolved, splitting into two new associations: the Pharmaceutical Industry Association of South Africa (PIASA) and the Innovative Medicines South Africa (IMSA).

PIASA was established as an association of companies involved in the manufacturing and marketing of medicines in South Africa. Its members were research-based MNCs and local manufacturers of pharmaceuticals. PIASA had about 90 members, consisting of both large and small companies. Other organizations, 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. In addition to this, the association tried to tackle regulatory hurdles that discourage investment in South Africa's biopharmaceutical sector. PIASA was also engaged in activities to influence the quality and cost of medicines, access to treatment, health insurance, drug laws and pharmaco-economic 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 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. Another important activity of PIASA was diffusion of knowledge through hiring consultants and providing members with expert advice on pertinent issues in the health innovation and regulation terrains. Such issues included standards for manufacturing facilities, drug registration fees and regulatory harmonization. This range of activities in the institutional context of South Africa indicates that PIASA played a crucial role in influencing the country's innovation system.

By contrast, IMSA was established as an industry association for research-based companies, even though some of its members also used to produce generics. This is not surprising; generics are crucial for the

public health service in the country. Among IMSA's members there were 12 MNCs who captured about 53% of the MNC market share in South Africa. Generally speaking, this biopharmaceutical association engaged in R&D policy, innovation regulation and lobbying. IMSA did not always perform such activities alone but in collaboration with other associations. Thus, for instance, in the PTG initiative IMSA played an active role in national health insurance issues, working jointly with PIASA and other public actors of South Africa. Another key focus of IMSA was on IPRs, especially access to drugs and marketing. The association worked with and through its members to exert influence on these issues. IMSA's key contacts in government were the 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. That is to say, it worked closely with government for the implementation of broader national policies by their members, for example requirements under the Black Economic Empowerment (BEE) programme.

The split of PMA into PIASA and IMSA was not the most negative consequence of the 'Big Pharma v Nelson Mandela' case. After all, in April 2013 these associations came together again, forming the Innovative Pharmaceutical Association South Africa (IPASA). It might be argued that the most negative consequence of the 'Big Pharma v Nelson Mandela' case was the damage to trust between government and biopharmaceutical associations. As one interview respondent pointed out,

[P]re-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 to 2004 which was all about weakening intellectual 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. (Interview extract: 23)

This statement confirms that, in South Africa, state-business relations (SBR) in the area of biopharmaceuticals remain fragile and therefore lack essential characteristics of effectiveness. According to Cali and Sen (2011: 1543), 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.

Clearly, South African SBR in the area of biopharmaceuticals are neither transparent and reciprocal nor credible and mutually trusting. Rather, due to the long-term impact of the 'Big Pharma v Nelson Mandela' case, these relations are based on mutual suspicion and distrust.

Analysis and discussion: resetting the state-industry relationships

Since its formation in 2013, IPASA has been engaged in a highly uneven relationship with government over the latter's policy plan to change the patent rules for medicines. 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 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). The South African government insists that the issue is not about weakening the TRIPS regime and the country's biopharmaceutical innovation system, but about implementing TRIPS with all the necessary flexibilities for the sake of public good (*The Economist*, 2014). The tension between government and IPASA (the majority of research-based pharma MNCs) heightened substantially when it was made known that IPASA was participating (perhaps leading) a campaign in collaboration with a Washington, DC-based public relations firm that aimed to promote the supposed adverse consequences of a weak IPR regime as proposed by the government, to target the South African public, business community and academic institutions. This bypassing of the government by IPASA in its attempts to thwart

government policy, and doing so during an election year, fuelled already high levels of distrust between the South African government and the research-based, primarily foreign-owned pharmaceutical companies.

The above episode is an apparent setback to relations that, while recently punctuated with conflict, have been defined more by increasing collaboration both within industry on key regulatory issues, particularly taxation and medicine registration procedures, and with government on broader health care policy. For example, a number of these biopharmaceutical industry associations have been involved more recently in wider policy discussions with government regarding science and technology workforce development, industry-university collaboration and the role of research-based pharmaceutical companies in the development and implementation of a South African National Health Insurance scheme. Resetting relations will require reengaging government on such issues, but huge differences on IPR will need to be addressed, if not wholly overcome. Even though stronger IPR laws are supported by much of South Africa's business community (e.g. SACCI supports a stronger IPR regime), the research-based pharmaceutical industry, due to its status as an important yet 'reluctant' and untrustworthy medicines provider, will need to go further. It needs to shed the perception that its interests in South Africa do not go beyond clinical trials and the profit-driven motive of protecting of its patented medicines and future therapies for sale not only in South Africa but the entire African continent.

For its part, the South African government needs to decide what type of role it sees the pharmaceutical industry playing in a relatively poor yet modern South Africa. On one hand, the South African government's approach to access to affordable medicines has indeed increased access, but has also resulted in a growing reliance on foreign generics (e.g. from India) rather than the development of a domestic generics industry. On the other hand, it has recently put forward public-private partnership (PPP) initiatives towards developing indigenous high-tech industries such as biotech, yet has not sufficiently articulated, at least in public, the role of IPR or the pharmaceutical industry in this new policy vision. This seeming contradiction is played out between government ministries, particularly long-standing divisions between the Department of Health, which supports weak IPR laws for ensuring access to affordable medicines, and Science and Technology (DST), which favours stronger IPR laws as a means of fostering innovation more generally and realizing the positive externalities that a robust research-based pharmaceutical

industry might provide South Africa. However, DoH and the Department of Trade and Industry (DTI) are aligned in the area of access to health. Such intra-government divisions, while justified, do complicate negotiations with industry and likely reinforce industry fragmentation between research-based MNCs and generics manufacturers. Current fragmentation on both sides of the negotiating table are contributing to tense relations between the South African government and the pharmaceutical industry and probably resulting in policy inertia and far less-than-optimal regulation.

Conclusion

In this chapter, we have considered the neglected role of industry associations in Africa as key intermediaries in innovation that, through evolutionary processes of conflict, negotiation and knowledge diffusion, facilitate institutional capacity building while shaping regulation and subsequent industry development. To do so, we have analysed the shifting strategies over time of biopharmaceutical industry associations and related organizations in South Africa. We have considered the importance of historically embedded relational dynamics between government and the pharmaceutical industry in South Africa involving critical junctures of regulatory uncertainty, mostly involving highly contested intellectual property regimes. Tracing developments during three main periods within different national context, our findings support previous research that suggests industry associations are more effective in lobbying and negotiating with government when industry is relatively cohesive and able to speak with one voice. This chapter, however, also suggests that in the case of the pharmaceutical industry, the extent to which industry associations can effectively engage with government is determined, in large part, by the willingness of government over time to neither demand nor capitulate, but to compromise with industry in ways that meet its own requirement for accessible medicines while recognizing the positive externalities of a robust domestic pharmaceutical industry. When such willingness is limited, either long-standing or temporarily, biopharmaceutical industry associations in South Africa are increasingly asserting themselves as 'partners' with government in attempts to correct these long-held tensions with the aim towards negotiating better policy outcomes.

In the case of South Africa, decades of tension between government and industry in general, which carried over from the apartheid era, have

exacerbated long-standing pharmaceutical industry fragmentation on key policy issues such as IPR, particularly those between MNCs and domestic generics companies. In turn, this has inhibited constructive policy dialogue and reinforced industry-government distrust, particularly regarding the pervasive assumption that the growth of an innovation-led biopharmaceutical industry in South Africa is incompatible with widespread access to effective and affordable medicines. Subsequent policy divisions between the DOH and DST both mirror the overall divisions and mistrust between industry and government and may contribute to regulatory inefficiencies. This has placed South Africa's biopharmaceutical industry associations, particularly those representing MNCs, often in direct and open conflict with government.

Finally, the historical trajectory and the shift to greater partnering strategies captured here provide insight into the conditions and processes through which 'growth coalitions' in developing countries such as South Africa either remain weak and ineffective in terms of developing a domestic industry or grow strong in that they effectively promote both the growth of domestic industry and the subsequent realization of positive externalities and spill-overs. In doing so, the challenges of moving government-industry relations to a more effective 'development coalition' model that is focussed on growth and poverty alleviation are laid bare. In the case of South Africa, the government and the pharmaceutical industry seem to be locked, based on decades of tension and mistrust, in a rather weak 'growth coalition' that, while promoting the interest of a few key industry players and keeping prices of medicines low, has kept the domestic South African pharmaceutical industry relatively small, dependent on foreign generic suppliers, with few positive externalities or spill-overs gained. For moving towards a stronger growth coalition, the biopharmaceutical industry associations of South African will need to build trust with government and to reconcile industry divisions among themselves.

Notes

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1. In total, 19 interviews were conducted, involving 4 industry associations: Innovative Pharmaceutical Industry Association (IPASA), National Association of Pharmaceutical Manufacturers (NAPM), South African Chambers of Commerce (SACCI) and South African Medical Device Industry Association (SAMEDI).



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