The Changing Role of South African Bio-pharma Industry Associations and Implications for Development of Healthcare Innovation Capacities

Theo Papaioannou, Andrew Watkins, Julius Mugwagwa and Dinar Kale

The increased importance of biopharmaceutical industry associations in influencing innovative economic performance in developing countries requires new thinking and policy regarding the institutions, which diffuse and govern knowledge in emerging contexts of economic and political pluralism. Based on a Leverhulme Trust funded research project, this policy brief considers the role of biopharmaceutical industry associations in building capacities for health innovation in South Africa. Empirical evidence from the project shows that biopharmaceutical industry associations in South Africa play an important role in shaping regulatory environments for medical technologies and, therefore, have the potential to contribute towards developing governance capacities for health innovation. However, this potential is conditional on reducing industry fragmentation and increasing collaboration with relevant public actors. For this reason, it is recommended that policies that facilitate greater partnering activities between biopharmaceutical industry associations, health care providers and government should be encouraged.

SOUTH AFRICA BIO-PHARMA: KEY STAKEHOLDERS AND INDUSTRY STRUCTURE

South Africa is biopharmaceutical industry forerunner in Africa, although its market worth R29.6bn in 2012 (approx. US$2.8bn) is relatively small and constitutes less than 1% of the global market. According to a 2013 industry report by Who Owns Who (Pty) Ltd, South Africa is one of a few countries where multinationals do not dominate the market and that in 2011, the two leading pharmaceutical companies in South Africa were locally-based, generic companies, Aspen Pharmcare and Adcock Ingram. Yet such companies import up to 90% of active pharmaceutical ingredients from other countries, including India and China. Overall, the South African pharmaceutical sector consists of the following categories of companies: multinationals with manufacturing facilities in South Africa; multinationals that import manufactured products in bulk; South African companies that import the packaged product; South African manufacturers contracted by multinationals to manufacture products, and; South African multinationals.

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 and South African multinational companies (producers of non-generics) are members of the newly-formed Innovative Pharmaceutical Association of South Africa (IPASA), while there is also the National Association of Pharmaceutical Manufacturers (NAPM), Self Medication Manufacturers Association of South Africa (SMASA), National Association of Pharmaceutical Wholesalers (NAPW), and the Southern African Generic Medicines Association, among others.

BIO-PHARMA ASSOCIATIONS: FROM INDUSTRY LOBBYING TO PARTNERING

The role of industry associations in shaping policy and regulatory environments through various lobbying activities is well established in the context of developed capitalist economies. In developing countries such as South Africa, however, industry associations can also be viewed as having the potential to fill institutional knowledge gaps and build governance capacities for innovation. This has particular relevance for the growth of biopharmaceutical industries in a developmental context where the confluence of needs for both new innovative technologies e.g. new medicines and affordable access to those technologies often comes into conflict.

Empirical evidence from this project shows that in South Africa, particular historical tendencies, including increasing pluralism, a lack in institutional capacities, and ongoing policy tension is gradually shifting industry associations from limited, often ineffective and controversial lobbying activities, to a new political approach that emphasises partnering with government, healthcare providers and other civil society organisations in the pursuit of not only narrow industry objectives, but also broader economic and development aims. Our research indicates that South African biopharmaceutical industry associations maintain a historically uneven relationship with government. This goes back to the 1998 ‘Big Pharma v Nelson Mandela’ case that damaged trust between industry associations and government. Since then efforts have been made in order for the relationship to be improved with industry associations employing a variety of strategies to pursue both industry specific and broader sector objectives. Such strategies range from direct lobbying activities to participation in government policy forums and select policy committees. In addition, these associations develop alliances with other actors of the health innovation system, including hospitals, health agencies and academia. Through such activities, biopharmaceutical associations, unsurprisingly, engage government primarily on regulatory policy concerning taxation, drug registration and pricing, clinical trials

1 https://shop.mcgregorbfa.com/content/Pages_from_33530_61394_62310a_-_The_Pharmaceutical_Industry_-_February_2013_-_Contents.pdf
and intellectual property rights, as well as manufacturing and marketing standards. In doing so, associations derive policy positions based on consultation with member companies, other aligned associations and umbrella organisations (e.g. major chambers of commerce), and international organisations such as the WHO and the IFPMA. In this way, these associations engage in knowledge brokering in their interactions with government and thus contribute, perhaps indirectly, to the building of institutional capacities. Importantly, a number of these biopharmaceutical industry associations have also been involved more recently in broader policy discussions with government regarding S&T 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.

**KEY MOTIVATIONS FOR CHANGE**

This apparent shift or diversification in activities by certain biopharmaceutical industry associations appears to be in response to long-standing and more recent tensions between the biopharmaceutical industry and government, particularly regarding IP protection on medicines, which in some respects has severely curtailed industry’s influence on government and led to regulation that is inefficient and counterproductive, e.g. overly long drug registration processes. This perceived conflict has pitted government, generic manufacturers, and civil society who favour less stringent IPR laws for ensuring affordable access to medicines, against research-based pharmaceutical companies, almost exclusively multinational corporations (MNCs) that are for a much stronger IPR regime; without which, they argue, South Africa will have less access to medicines, against research-based pharmaceutical companies in South Africa. In order to achieve the expressed objectives, however, policy makers will need to come up with specific measures to tackle challenges that are rooted in historical tensions, legitimate policy differences, and general mistrust. These challenges include:

**POLICY IMPLICATIONS**

Overall, a slow yet gradual shift appears to be emerging in South Africa where biopharmaceutical industry associations are engaging in partnering activities with government. In South Africa, such partnering practices are newly emerging and not yet institutionally embedded. Furthermore, how genuine and serious this shift in approach is has yet to be critically assessed. That being said, policy should facilitate trust building between industry associations and appropriate government ministries; expand upon existing industry and government collaboration and forge more effective public-private partnerships (PPP) in local production of medical technologies, healthcare delivery and infrastructure. This has the potential to better build institutional capacities for health innovation and develop a more effective and responsive biopharmaceutical industry in South Africa. In order to achieve the expressed objectives, however, policy makers will need to come up with specific measures

**POLICY RECOMMENDATIONS**

On the basis of our empirical research findings, we make the following policy recommendations:

- Facilitation of more effective collaboration between MNCs and domestic companies when negotiating industry aims with government, e.g. discourage single issue lobbying by individual companies or associations by requiring that formal policy positions be based on industry consensus;

- Support for more effective and inclusive forums that facilitate constructive dialogue between industry, government and civil society, particularly around the issues concerning innovation and access to affordable medicines, showing that innovation-led industry growth and greater access to medicines are not mutually exclusive goals;

- Reform government’s policy process in ways that better integrate innovation and health care systems, and streamline the activities and interactions between DOH, DTI and DST;

- Support for efforts to develop S&T infrastructure, particularly through PPP aimed at developing a more robust S&T workforce and creating more effective university-industry linkages with significant connections to global knowledge flows. Such efforts might better incentivise collaboration and knowledge transfer between industry and government in a way that better articulates and realises the complementarities between the two.

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2 International Federation of Pharmaceutical Manufacturers and Associations

Contact author:
The authors are researchers based at the Innogen Institute, Development Policy and Practice Group, The Open University, Walton Hall, Milton Keynes, MK7 6AA, UK

t - +44 (0) 1908 654782 e - t.papaioannou@open.ac.uk