The Role and Potential of Indian Bio-pharma Industry Associations in Strengthening of Healthcare Innovation Capacities
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This policy brief considers the role and potential of biopharmaceutical industry associations in building capacities for health innovation in India. Empirical evidence from the project indicates that biopharmaceutical associations and related umbrella organisations play a critical role in informing government on regulation and standards, having forged an uneven yet productive relationship with government that has contributed to a robust and dynamic Indian biopharmaceutical industry. However, further developing India’s biopharmaceutical industry in a way that both builds its globally competitive innovation capacities while effectively addressing its local healthcare needs will require greater trust and transparency and more complimentary relations between industry and government and civil society. For this reason, it is recommended that policies that facilitate platforms for collaboration geared toward inclusion, substantive knowledge exchange, simplification of policy and regulatory processes, and the promotion of risk finance should be encouraged.1

INDIAN BIOPHARMA: KEY STAKEHOLDERS AND INDUSTRY STRUCTURE

The Indian biopharmaceutical industry is a world leader with a market value of nearly US $18bn in 2012 and according to a McKinsey and Company report is projected to grow to nearly US $40bn by 2020.2 3 As a major manufacturer of generic medicines and increasingly a developer of patented medicines, India has become ‘…one of the world’s largest suppliers of vital medicines and vaccines’ (Srinivas, 2012: 10).4 In fact, over the last decade much of the rapid growth of Indian biopharmaceutical industry has been driven by local companies, based on superior process R&D capabilities, technological innovations in manufacturing drugs and vaccines and access to generic markets in advanced countries. Overall, the Indian biopharmaceutical sector consists of the following types of companies: large Indian MNCs that manufacture generics for domestic use and export; foreign MNCs that manufacture generic and patented medicines in India, mainly through Indian based subsidiaries; small to medium sized Indian manufacturers that are often used by the larger companies for outsourcing; a limited yet growing number of small Indian biotechnology oriented companies that produce for both domestic and foreign markets.

With respect to industry associations, Indian biopharmaceutical companies are represented by a number of industry specific associations. These include the Organisation of Pharmaceutical Producers of India (OPPI), Indian Drug Manufacturers Association (IDMA) and Indian Pharmaceutical Association (IPA), as well as the Association of Biotechnology Led Enterprises (ABLE). Each of these organisations represents interests of a particular group of firms; OPPI membership is dominated by MNCs, IDMA represents small and medium sized domestic firms (SMEs), while IPA acts as a business organisation that includes the top 11 Indian pharmaceutical firms as members. ABLE represents the interests of a growing number of biotech SMEs. In some instances, companies will be members of multiple associations. Indian pharmaceutical companies, as well as industry associations, are also represented by large Indian umbrella organisations and chambers of commerce. In this regard, the primary organisations are the Confederation of Indian Industry (CII) and the Federation of Indian Chambers of Commerce and Industry (FICCI). These organisations represent the Indian pharmaceutical industry in negotiations with government, but more often as part of a much broader coalition of industries.

Post-independence, the Indian government has played a key role in development of the local biopharmaceutical industry through various regulatory and industrial policy interventions. Empirical evidence from this project shows that, historically, cooperative relations between the Indian government and the Indian pharmaceutical industry have been essential toward developing India’s robust and diverse biopharmaceutical industry. The Indian government’s commitment to developing an indigenous pharmaceutical industry resulted in The Patent Act of 1970, which eliminated patent protection on pharmaceuticals in India. This spurred the rapid growth of India’s generic medicines industry and its capacities for reverse engineering, while dramatically lowering the price of medicines in India and in other developing countries through the export of Indian medicines.

1This paper draws on a research project, ‘Unpacking the Role of Industry Associations in Diffusion and Governance of Health Innovations in Developing Countries’, funded by The Leverhulme Trust UK, during 2013-15, reference number RPG-2013-013.
2IBEF: http://www.ibef.org/industry/pharmaceutical-india.aspx
That being said, the 1970 Act also resulted in the pull-back of research based MNCs from India. The Indian government’s liberalisation policies of the 1990s and India’s subsequent ascension to the WTO resulted in further growth both for the Indian economy and the Indian pharmaceutical industry. India’s pharmaceutical industry, as represented by respective associations, was deeply divided, however, over the adoption of TRIPS, which required India to adhere to an internationally-agreed intellectual property rights regime. Ensuring adherence to TRIPS while protecting its generic medicine manufacturers, the Indian Government negotiated a TRIPS transition agreement that extended the deadline for full TRIPS compliance to 2015. This agreement was also in line with the critical views of civil society organisations and therefore legitimised. This change in regulatory environment drove local Indian firms towards innovative process R&D and led to entry of MNCs in the Indian domestic market, bringing changes to the objectives of industry association.

INDIAN BIO-PHARMA ASSOCIATIONS: FROM INDUSTRY GROWTH TO INNOVATION IN HEALTHCARE

For developing countries such as India, industry associations can act as key intermediaries in filling institutional knowledge gaps between industry and government that shape regulation and have the potential for building institutional capacities for both innovation and development. The extent to which industry associations can influence regulation and policy in this way is conditioned on their ability to both build industry coalitions and forge collaborative relations with a receptive, but often sceptical government. This is particularly challenging in the case of biopharmaceuticals within a developing country context, where governments’ need for affordable medicines and accessible healthcare at times conflicts with industry’s interests in developing and selling innovative, often expensive, new medicines and medical technologies. This potential fissure can result in industry fragmentation, generally between generic manufacturers and those companies that are research focused. This can contribute and reinforce tensions between industry and government, leading to ineffective regulatory policy and the forgoing of positive externalities that could be realised through industry innovation and growth.

As such, our research indicates that Indian biopharmaceutical industry associations maintain a collaborative yet uneven relationship with government that while emphasising industry growth has been punctuated by more recent periods of mutual distrust and tension. The TRIPS compliant patent regime and the increasing size of the Indian healthcare market has led to changes in the priorities of different stakeholders, creating a chaotic context for policy formulation as evidenced by controversies over clinical trial regulations, issuance of compulsory licensing and price control orders. For their part, government and civil society, at times, have accused the pharmaceutical industry elites of pursuing their own narrow interests at the expense of not only Indian consumers, but also the health and wellbeing of citizens. In 2013, on the directive of the Supreme Court, the Indian government temporarily halted all clinical trials, citing numerous ethics violations, the significant number of deaths related to clinical trials, and the need for more rigorous regulation and oversight. New guidelines for clinical trials have been put forward, but these have not been well received by industry, particularly the research based companies that have argued that the new guidelines and regulations are too restrictive and will hurt India’s ambition to become a ‘drug discovery and pharma innovation hub’. Other areas of contention with government policy, which often break down between the generic manufacturers represented by IDMA and the research based companies represented by OPPI, include disagreements over intellectual property and full TRIPS adoption and related issues regarding compulsory licensing and price controls. Where the Indian pharmaceutical industry is more united, however, is in its frustration with Indian bureaucracy and the complicated process of registering new drugs, re-licensing existing drugs, and standardising drug manufacturing, packaging, and marketing. In India, the regulation of pharmaceuticals falls under not only a dozen or so ministries at the national level, but the manufacturing and distribution of pharmaceuticals is overseen by State governments. These complexities cause delays, increase the costs in introducing new medicines, and can hamper standardisation and quality improvement efforts. Past attempts at centralising the pharmaceutical regulatory process have been negotiated but never implemented (e.g., the 1994 Drug Policy and the 1999-2003 Mashelkar Committee).

KEY MOTIVATIONS FOR CHANGE

It is clear that historically cooperative yet uneven industry-government relations in pharmaceuticals has placed the Indian pharmaceutical industry on a trajectory that has emphasised the building of its generics medicines capacity over its capacities for research and development. This has led to the remarkable growth of India’s pharmaceutical industry and reduced the price of medicines, but this approach has largely failed to address continued systemic weaknesses to both India’s capacities to develop new drugs and to provide inclusive healthcare. The Indian healthcare system is under considerable strain due to pervasive and widespread poverty and increasing inequality. In addition, it suffers from a lack of sufficient healthcare infrastructure, with much of India’s population, particularly in rural areas, still without adequate access to life saving medicines and quality routine medical procedures. Within this broader context, our research shows movement toward addressing some of these weaknesses through greater collaboration and knowledge exchange. One example of this is the Biotechnology Industry Research Assistance Council (BIRAC), which acts as an intermediary and facilitates partnerships between the Indian government and India’s biotechnology industry (ABLE as a main participant), with the aim of creating healthcare solutions appropriate and affordable for local populations. Another example is the India Innovation Growth Programme that is sponsored by India’s Department of Science and Technology (DST) and Lockheed Martin with participation by Indian and US universities, as well...
as FICCI. This programme is aimed at assisting Indian entrepreneurs in commercialising innovations for global markets. Going forward, however, the extent to which such programmes can be leveraged or refocused to address domestic needs concerning accessibility to new medicines and technologies must be considered.

**POLICY IMPLICATIONS**

Overall, India’s biopharmaceutical industry is poised to experience continued growth and to solidify its position as a global leader in biopharmaceuticals. That being said, building and maintaining a globally competitive biopharmaceutical industry, while both realising positive externalities and dramatically increasing healthcare quality and access for all Indians, will require greater collaboration between the Indian pharmaceutical industry and the Indian civil society and government. The focus of which should be on reorienting or rebalancing industry policy and regulation from a primarily growth oriented agenda to one that emphasises domestic development of innovation capacities and increasing accessibility to quality healthcare.

In order to achieve the expressed objectives, policymakers and the industry associations themselves, in taking the lead, will first need to come up with specific policy measures and engagement strategies to overcome certain path dependencies, general mistrust between industry and civil society and government, legitimate policy differences, and historically embedded complexities regarding policy processes and regulatory inefficiencies. These challenges include:

- A lingering distrust and lack of transparency between government and the pharmaceutical industry that goes back to longstanding tensions regarding IPR and compulsory licensing and to more recent controversy surrounding clinical trials in India.

- An overly complex and cumbersome regulatory decision and implementation process for biopharmaceuticals that involves several authorities at both the national and state level.

- Knowledge and interest barriers between industry specific associations such as OPPI and broader umbrella organisations such as FICCI. These barriers inhibit more substantive knowledge exchange between them and can limit industry’s overall access to government.

- A pharmaceutical industry that is dominated by large companies that are not necessarily R&D focused, coupled with a significant lack of risk finance for supporting new ideas, scientific talent and entrepreneurial firms in the life sciences, medical devices and biotechnology.

**POLICY RECOMMENDATIONS**

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

- **Government needs to identify and approach biopharmaceutical industry associations as not just representing industry’s interests, but as primary sources of information regarding industry needs and requirements that can effectively inform appropriate regulatory environments and innovation policy more generally:** better incorporating the pharmaceutical industry into broader coalitions for both Indian development and innovation capacity building.

- **Government should work with industry on streamlining the pharmaceutical regulatory process, with the aim of consolidating several ministry functions into a single ministry or agency, as was negotiated but never implemented under the 2003 Mashelkar Committee Task Force.** Such efforts would go a long way to addressing complexities and regulatory inefficiencies caused by different national and state held regulatory approval and implementation processes.

- **Biopharmaceutical industry associations should engage more with umbrella organisations such as FICCI and CII and their wider development agendas, both adopting and shaping these development aims through formal and informal collaboration.** Such platforms could be used to more effectively to engage civil society and government on issues concerning innovation and development.

- **Biopharmaceutical industry associations, umbrella organisations, civil society and government need to find ways to work together to promote the supply and accessibility of risk finance schemes, including venture capital, for supporting new entrepreneurial firms in the life sciences, medical devices and biotech.** Such efforts might include various public-private partnerships, as exemplified by BIRAC that include Indian universities, large corporate collaborators, and venture capital from abroad.

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