



INDIAN THOUGHT LEADERS' POLICY DIALOGUE ON HEALTH, INNOVATION AND COMPETITIVENESS

MUMBAI, OCTOBER 2018

INTRODUCTION

The Indian government has prioritised the promotion of innovation and competitiveness to meet the country's economic and social objectives, including in the health and life sciences sectors. To feed into this discussion, Geneva Network organised a half-day round table on October 11, 2018 in Mumbai to assess the state of play, and also to brainstorm policy reforms that could accelerate progress. The round table included 15 thought leaders from Indian think tanks, universities and NGOs, in addition to participation from around 20 individuals from the private sector.

A significant focus of the discussions was the reforms necessary to promote innovation and to make India a leading life science investment destination. The conversation covered intellectual property, regulation and trade policy, with a particular reference to the lessons that can be learned from China's recent reforms to its intellectual property and medicines regulatory frameworks.

INNOVATION, INTELLECTUAL PROPERTY AND COMPETITIVENESS

A key focus of the discussion was the linkages between innovation and economic development. State-level data was shown illustrating that innovative states such as Tamil Nadu, Karnataka and Maharashtra have higher GDP levels than less innovative states, a relationship that also holds true for cross-country comparisons. At an international level, participants presented data demonstrating India's relative underperformance, with China in particular outpacing India on most innovation-pertinent input and output measures. China spends 12 times more on R&D than India, for instance.

Participants agreed that policy makers should accordingly focus on creating the policy frameworks that will facilitate the growth of innovative and creative industries. Prospects for the Indian economy will be further enhanced if it can become a global innovation hub, an ambition that will require a holistic approach to reform. Participants agreed that government's immediate focus should be on strengthening the enablers of innovation, notably the intellectual property framework. This will allow India to bolster its innovative capacity by integrating more meaningfully with global value chains, notably in the life sciences sector. In addition to bringing much needed foreign direct investment, greater participation in global value chains will bring increased levels of technological and managerial know-how to Indian companies.

It was agreed that a framework of clearly defined and easily enforceable intellectual property rights is central to this ambition. Increasingly, Indian companies are also looking for certainty and transparency in the IP framework, not just multinational companies.

Participants identified two specific issues around intellectual property that are currently undermining India's ambitions to bolster its innovative capacity:

- Section 3(d) of the Patents (Amendment) Act of 2005, which sets a higher standard of patentability for pharmaceutical inventions, is affecting the ability of both foreign and domestic companies to invest in innovation. It was noted that Indian generic companies are filing patents on incremental innovations in overseas jurisdictions, but not in India where these inventions would be unpatentable under Section 3(d). This aspect of Indian intellectual property law could therefore be hindering the ability of generic companies to transition their innovative capacities from simple reverse engineering of existing medicines towards more value-added R&D. Additionally, it is also possible that it is impacting foreign investment
- Participants also noted how the ongoing threat of using compulsory licenses to achieve general public health goals is chilling investment, and it was observed that many investors avoid the Indian market due to this risk

Reforms to these areas are particularly urgent given the seriousness with which major competitor China has been addressing shortcomings in its own intellectual property framework. For instance, China has recently instituted a patent linkage system, strengthened its system for the protection of clinical trials data, and introduced patent term extensions to compensate for delays in the mandatory drug approval system.

Recommendations:

- Reform Section 3(d) of the Patents Amendment Act of 2005 to incentivize Indian biopharmaceutical companies to invest in innovation in India
- Ensure that the use of compulsory licenses is transparent and predictable

IMPROVING THE QUALITY OF REGULATION

Private sector participants noted that the Indian regulatory framework is unpredictable, with changes made often at short notice and in an arbitrary manner. There is also a lack of coordination between different ministries and departments that add to the burden and cost of drug approval. It was particularly noted that current regulations do not allow Phase I studies for drugs discovered outside of India, which creates a significant hurdle for introducing new medicines into the country. And while India recently achieved observer status at the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), it was noted that representatives from the Indian drug regulatory agency do not regularly participate in ICH meetings, a requirement to be considered as a full member. Collectively, these factors add up to an unfriendly regulatory environment that affects foreign investment in the Life Sciences sector.

Participants contrasted this with China's recent impressive performance in attracting foreign investment into its Life Science sector, and the rapid reorientation of its domestic companies from generic manufacturing towards innovation. China's central government has recently spearheaded a wide range of reforms to the regulatory framework to facilitate this transition. The drug regulatory authorities have significantly reduced the time it takes to approve a new medicine, and domestic companies failing to meet the required standards are being shut down to improve quality. This regulatory upgrading has been accompanied by a significant increase in staff at the Chinese drug regulator. Simultaneously, the Chinese market has been opened to foreign contract management organisations, with incentives to promote foreign

investment. China has recently begun to accept results of overseas clinical trials, and the national regulator is a full member of ICH and on the ICH management committee, giving the country a leadership position in developing regulatory frameworks at the international level.

Recommendations:

- Simplify the process of drug approval in order to decrease drug approval timelines. A particular focus should be placed on biosimilars, whose regulatory approval processes are opaque. Extend the capacity of the existing SUGAM portal developed by CDSCO to an inter-ministerial approval portal for uploading documents and tracking status of clinical trial applications in biologics and genetically engineered products as well
- Further reduce regulatory bottlenecks by obliging the regulator to accept clinical trials data generated overseas in the drug approval process. The government could consider conditionally allowing overseas trial data in support of drug registration in India and providing potential conditional approvals based on early/mid-stage trial data
- Bolster the capacity of national and state regulators to address shortcomings in expertise and manpower
- Move towards India becoming a full member of the International Council for Harmonisation

CREATING A MORE COMPETITIVE MEDICINES' MARKETPLACE

Participants noted that tariffs on medicines, supply chain costs and mark-ups and other non-tariff barriers are more important than patent status in determining the end price of medicines to patients. A study was cited which estimated the annual compounded financial burden of import tariffs on pharmaceuticals and prevailing trade facilitation inefficiencies for India amounts to USD 737 Mn and the tariffs on medicines increase their final price by up to 80 per cent of the original sales price ex-factory. India maintains one of the highest import tariff rates in the world, at around 10% on average across a wide range of imported medicines and vaccines. Meanwhile inefficiencies in ports, customs procedures and state borders add to the costs of moving a medicine to the point of patient delivery. Taken together, these barriers to trade undermine the competitiveness of the Indian market, inflate end-user prices and may have a negative impact on access to medicines.

Recommendations:

- Rationalize tariffs on imported medicines and vaccines
- Investigate trade facilitation reforms that would ease cost-increasing bottlenecks and alleviate the compounding impact of mark-ups at different levels of the supply chain

IMPROVING DEMAND FOR INNOVATIVE LIFE SCIENCE PRODUCTS

Participants noted that investment in R&D and the quality of health interventions are severely undermined by a fundamental lack of data. This lack of data makes it difficult for stakeholders to quantify demand for medicines accurately, meaning that resources are not effectively allocated. Specific shortcomings were identified in the quality of data relating to state level healthcare spending; spending by disease; and the effectiveness of existing interventions.

Recommendations:

- The private sector possesses considerable amounts of useful data that is not commercially sensitive. A data-sharing partnership between the private sector and government should be developed so that demand can be understood more clearly and interventions better targeted
- Digital Information Security in Healthcare Act Draft calls for setting up National e-Health Agency [NeHA] and State e-Health Agencies [SeHA], obliged to promote setting up of state health records repositories and health information exchanges (HIEs) to facilitate inter-operability. Augmentation of the roles of these agencies to ensure patients' data can be tracked at a granular level



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