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27 Mar 2023 | **Analysis**

What Pharma CEOs, PEs Want To Move The Innovation Needle In India

by Anju Ghangurde

Leaders of biopharma and private equity firms at a recent conference sought a robust domestic market and reimbursement mechanism to propel the innovation ecosystem in India, drawing parallels with the framework that aided China's ascent in the R&D value chain. Alongside, regulatory reform is also pivotal, they stressed.

Industry heads at a recent conclave discussed some of the key issues weighing on India's ascent up the innovation value chain including the criticality of a robust domestic market for novel products, an effective reimbursement mechanism and regulatory reform as part of developing the overall ecosystem.

Glenmark Pharmaceuticals Limited's chairman and managing director Glenn Saldanha emphasized that the government needs to play an important role in reimbursing expensive, novel products coming out of India.

"That will create an ecosystem - China did pretty much the same thing. Basically, China promoted their local innovation by the government reimbursing expensive, patent protected products through the system," Saldanha said at a panel discussion at BioAsia 2023 in India. (Also see "*BioAsia 2023: Leaders from Novartis, Apple Talk Innovation, Tech, Data Privacy*" - Scrip, 28 Feb, 2023.) (Also see "*GSK CTO, Boehringer Exec On The Metaverse And Pharma's Foot In The Door*" - Scrip, 9 Mar, 2023.)

The Next Frontier: How India Could Up Its Game In Biopharma Innovation

By Anju Ghangurde

22 Nov 2021
Industry leaders and experts, including executives from McKinsey, Eight Roads Ventures and Novartis, share global best practices, insights and expectations around

There has to be some reimbursement system for India-developed innovative products, which will be compared to "world benchmarks" and be at a premium to the generic or the branded generic drugs available in the country, he elaborated.

how India could accelerate its journey towards becoming a biopharma innovation hub.

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"That will be one mega change, which I think is essential if you want to kickstart the Indian innovation system," the executive declared.

While government is doing "a lot", rolling out initiatives such as the Production-linked Incentive (PLI) and details of a research-linked incentive scheme are anticipated, Saldanha maintained that a domestic market for home-grown innovation was missing as such.

China, he reiterated, had created that domestic market, which spurred innovation as it ensured local drugs get reimbursed especially in areas of high-end oncology and certain other unmet medical needs. "That's a critical element," Saldahna added.

In 2020, India outlined details of a PLI scheme for manufacturers of certain critical APIs and drug intermediates in the country, while subsequently another such scheme sought to enhance broader manufacturing capabilities and facilitate "product diversification to high value goods" in the pharmaceutical sector. (Also see "*India APIs Incentive Scheme: Will It Galvanize Local Firms, Bridle The Dragon?*" - Pink Sheet, 8 Jun, 2020.) (Also see "*Will The $3bn Stimulus Amid COVID-19 Place Indian Cos Among Goliaths?*" - Scrip, 12 Mar, 2021.)

The RLI scheme is expected to provide a similar cushion for innovation efforts – moon shot areas expected to be covered include complex generics, precision medicine and orphan drugs, among others. In 2021, India had put forth a wide-ranging draft policy plan to spur R&D and innovation in the biopharma and medtech segments, recognizing the need to evolve beyond its traditional strength in generic medicines and also build world-class innovation capabilities. (Also see "*India Proposes Faster Approvals, Bayh-Dole-Like Policy To Spur Innovation*" - Pink Sheet, 2 Nov, 2021.)

The impetus for pharma R&D has the attention of the country's top leadership. India's finance minister Nirmala Sitharaman had in her budget speech for 2023-24 referred to a new program to promote research and innovation in pharmaceuticals that will be taken up via centers of excellence. "We shall also encourage industry to invest in R&D in specific priority areas," the minister said earlier this year. The wider aim is to progress industry from cost-based to innovation-based growth.

Captive Domestic Market

Other panellists too emphasized that a robust domestic market for novel products was instrumental to catalyze innovation.

> *"Once you have a captive domestic market, then you can even attract investors into the discovery model. Otherwise, you're saying to them, 'choose India over a discovery company in the US to innovate.'" - Biological E's MD Mahima Datla*

Biological E Limited.'s managing director Mahima Datla explained that the lack of a domestic market in India for such innovation was a reflection of inadequate health insurance coverage – where even for those covered "it's moderate and the cap is very low."

"It doesn't allow for mRNA/gene therapies, any kind of innovative products," she stated.

Around 30% of the Indian population do not have adequate financial protection for health, though the central government's Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) launched in September 2018, and state government extension schemes, is estimated to provide comprehensive hospitalization cover to the bottom 50% of the population – around 700 million individuals. (Also see "*Can Modicare Reshape India's Health Care Paradigm?*" - Scrip, 27 Nov, 2018.)

Neither does India have procurement mechanism like the UK's National Health Service (NHS) or the US Centers for Disease Control and Prevention that provide an opportunity to make such novel therapeutics accessible.

"If you're saying just discover a product but export it or make it available only to those who can afford it - that's a different business model. That could be a pure play CDMO [contract development and manufacturing] opportunity and if that's the case, we're already well positioned," she maintained.

But for innovation that creates products that can be consumed domestically, the demand for that is driven by "policy intervention."

"Once you have a captive domestic market, then you can even attract investors into the discovery model. Otherwise, you're saying to them, choose India, over a discovery company in the US to innovate and I'm not sure what the value proposition there would be."

Satish Reddy, chairman of *Dr. Reddy's Laboratories Ltd.*, added another dimension, suggesting that the government can perhaps pitch in via a joint funding mechanism for early stage innovation efforts so that venture capital firms can then come in.

“At least then you get started somewhere and this is a model practiced in certain other countries, like Israel, for example, that have this kind of system,” Reddy said at the panel discussion.

Israel, for instance, under an initiative between 1993 and 1998 provided capital, co-funding up to 40% new funds set up in the country, though that mix has over time shifted more to the private sector as the ability to fund itself has been achieved. China too has over the past provided a significant part of the capital that is available in the VC pool through governmental funding.

Reddy also noted that while Indian companies continue to adapt to global pressures, diversifying into new markets/product areas and building on its play in the promising biosimilars space, if firms have to really be 'relevant' in the long term, promoting innovation holds the key.

“Unless we do that, I think we will miss the bus if we don't act quickly.”

Gap In Market Creation

The assessment by Indian industry heads is in sync with what venture capital and private equity firms have been saying for a while now.

Sunil Thakur, partner at Quadria Capital, a healthcare focused private equity firm, said that PEs typically like to go behind opportunities or technologies that they see are going to be the “future winners” but tend to “pause” when it comes specifically to the new age therapies in India when they consider the entire circle of R&D to market creation.

“The biggest gap that we see in India is market creation, because ultimately, we are investing for commercial reasons. Whatever is being developed and invested in has to be sold in the market. That's the biggest roadblock that we currently see in the market,” Thakur said at another session at the BioAsia conclave.

Thakur also noted that the innovation ecosystem in India currently seems a “bit fragmented”, with “lots of friction points”. While India does have the requisite scientific base, capacity and capability in the ecosystem as also the skills, these are currently completely fragmented, he explained.

The executive, who comes with wide-ranging transaction experience across the Asia-Pacific market, also called for regulatory capabilities that need to be “very progressive and predictive” at a session on “Data, analytics and technology to transform drug R&D: Redefining innovation.” sponsored by *Citeline*. (Also see "*Immuneel COO On Benchmarking The Firm’s CAR-T Against*

Mature, Global Data Sets" - Scrip, 20 Mar, 2023.) (Also see "*India Trials And Tribulations: J&J, IQVIA Execs Offer Potential Solutions*" - Pink Sheet, 7 Jul, 2022.)

> *"The biggest gap that we see in India is market creation, because ultimately, we are investing for commercial reasons." - Sunil Thakur, partner, Quadria Capital*

Dr Prem Pavoor, partner and head of India for Eight Roads Ventures, a global investment firm backed by Fidelity, had previously similarly highlighted that the "mantra" for VC investors is one where they'd like to see a large market, talent and exit opportunities "at some point."

While it may be okay to have an innovation landscape that is dependent on the western market for commercialization, Pavoor said it is "better" if there is also a domestic market that is large enough for these companies to be able to commercialize their products.

"That will catalyze the innovation ecosystem; we've seen that in China and the US," Pavoor had said at an innovation summit in India in 2021.

Robust Procurement, Disbursement Mechanism For Vaccines

Back at BioAsia 2023, Biological E's Datla also went on to contrast dynamics, in general, for the vaccine industry in India, where majority of the pediatric vaccines are fully funded and reimbursed or given free by the government.

Here government policies have been "extremely strong" because it's the "most cost-effective intervention available" and newer vaccines including the pneumococcal conjugate vaccine are among those being rolled out.

"In the vaccine industry, we're very fortunate that when you say domestic market, there is a very robust procurement mechanism and disbursement or access mechanism," she pointed out.

This "very successful mechanism and distribution channel" that already existed for pediatric vaccines came in handy during India's massive Covid vaccination effort.

But in the broader industry context, it boils down to the "push and pull" mechanisms, Datla specified. While push initiatives like the PLI/ RLI schemes are definitely "great incentives" for the biopharma industry, pull mechanisms are equally important, the executive noted.

Even in the vaccines space, while Biological E has just launched a 14-valent pediatric pneumococcal conjugate vaccine and is developing a 24-valent conjugate vaccine, “we don't know if that will be adopted, or if that will automatically be in the government procurement mechanism.”

“That will dictate quite directly what the demand for those products will be. So there's that gap that exists in the context of vaccines,” Datla pointed out.

For innovative drugs the pull mechanism is much more important, she underscored highlighting the need to create that system through effective procurement or via reimbursements by broadening insurance.

Regulatory Reform

Importantly the industry heads also called for a regulatory revamp to attract capital so that companies can take more calculated risk in R&D across the spectrum all the way from start-ups and small scale firms to medium scale and even the larger players.

Panellist, Hari Bhartia, founder and co-chairman of the Jubilant Bhartia group, suggested that Indian firms could target developing follow-on drugs, but alongside highlighted the need to streamline trial and regulatory approval timelines in India.

Bhartia also drew attention to how China is now discovering drugs for its home market and not necessarily for the US. “We need to discover drugs for India, for Indian patients, and do the trials on Indian patients. That way you can bring the price down to 1/20th or even 1/50th in many cases. That is a big opportunity,” Bhartia asserted.

Besides ensuring faster approvals, Dr Reddy’s chair Satish Reddy stressed the need to address core regulatory capacity across both the central and the state system in India. While most functions pertaining to biopharma regulation including clinical trials and laying down standards for drugs come under the purview of India's Central Drug Standards Control Organization (CDSCO), areas such as licensing and monitoring of local manufacturing units and distribution of drugs are primarily regulated by the State Drug Control Authorities. (Also see "*2021 Saw India Enable Accelerated Regulatory Pathways – Can It Become The Norm?*" - Pink Sheet, 13 Jan, 2022.)

"A whole host of issues need to be looked into to ensure that there’s confidence not just from a pharma company's point of view, but ultimately the patient's point of view - finally they need to get the confidence,” Reddy emphasized.

Reddy said that India’s Drugs and Cosmetics Act itself needs to be amended because “what we have in place is something that started way back.” Last year, India had proposed a draft New Drugs, Medical Devices and Cosmetics Bill, 2022 as it seeks to “keep pace with changing needs,

times, technology."

Reddy also called for coordination among Indian states, so that regulation is done in a "concerted" way.

"It can't be that one state has a certain interpretation and implementation of the law compared to the rest of the states," Reddy stated.

Policies, including "frameworks for inter-departmental co-ordination", are in the works, government functionaries have indicated and are expected to address some of these issues.

Further, Reddy also pointed to the need for consistency on the enforcement front – certain states are seen as probably "lax" in this area. "But the most important thing is in terms of building capacity and capabilities within the regulatory system - that needs a lot more to be done," Reddy added.

Biological E's Datla similarly called for harmonization on regulatory oversight but brushed away any wider concerns of an erosion in trust in the quality of Indian drugs; this in the backdrop of recent headlines around medical product alerts by the World Health Organization against the use of contaminated cough syrups made by two local firms that have been alleged to be linked to death of children in Gambia and Uzbekistan. (Also see "*The Quality Lowdown: The Effort Required To Stem Substandard, Illegitimate, Unapproved Drugs*" - Pink Sheet, 13 Feb, 2023.) (Also see "*Amid US Cough Syrup Findings, Regulators Feel India Needs To Work On Perceptions But Also Make Improvements*" - Pink Sheet, 15 Mar, 2023.) (Also see "*Data Integrity And The Iceberg Concern*" - Pink Sheet, 17 Oct, 2018.)

"They're [the regulator] are sort of the custodians to ensure that industry is not making trade-offs between quality and exigencies related to demand. So, they really need to be true custodians, and have harmonization," Datla added.

Bringing Talent Back

Panelists at BioAsia also drew attention to India's talent pool and the need to perhaps attract high quality personnel back home, along the lines of China's "Thousand Talents" program.

Piramal Pharma's chairperson, Nandini

India's 'Thousand Talents' Moment And Models To Shift Gears In R&D

By Anju Ghangurde

24 Nov 2021
Industry leaders including Sanofi's ex-CEO and the chiefs of Sun, Lupin, Glenmark, Dr Reddy's and Cipla discuss how India could leapfrog its pharma R&D efforts. Could the South Korea model or a hybrid approach including bringing back top talent bolster the

Piramal, said that India needs to take advantage of some of its "natural assets" - very skilled people, several of who have been in industry both in India and outside.

Piramal referred to how China could woo its nationals who worked overseas to come back and start companies.

country's efforts to emerge as a global innovation hot spot?

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"Our people are some of the best in the world. I also think that in an era of 'China Plus One' where people are beginning to think that they need to do innovation somewhere other than China, India is also a great place to do that," Piramal asserted.

Glenmark's Saldanha similarly added that in addition to fixing gaps in the regulatory system, building industry-academic partnerships, India should seek to draw back its intellectual capital, "particularly people who are of India origin in the US" to the country and provide them an ecosystem to upskill the overall talent pool.

Overall, though, he maintained that India is on course to build its innovation ecosystem - whether it's at the government level, through the RLI scheme, or getting its regulatory systems together.

"There are multiple changes happening in India. This decade looks very promising in terms of actually coming up with something novel out of the country," he declared.

Glenmark has been engaged in research in new molecular entities since 2002 and has signed out-licensing deals worth about $300m for some of its novel assets since. The Mumbai-based firm has a rich pipeline of products including a multi-specific oncology pipeline being developed by its innovation arm *Ichnos Sciences, Inc.* though it has yet to debut a fully home-developed drug on the global stage. (Also see "*Ichnos CEO On The 'ASH Of Bispecifics', Progress With Trispecific*" - Scrip, 22 Dec, 2022.)