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Presenting India as a 'Bio-manufacturing Hub': Are we ready?

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Presenting India as a 'Bio-manufacturing Hub': Are we ready?

Industry leaders believe that the negativity created by prevailing regulatory environment and unending controversies, have led to under performance of the biotech sector. However the renewed focus on producing quality Indian products has brought to fore a hidden opportunity to show its importance in the new context.

To begin with, it is the time multinational companies working in India should stop maligning image of the country, mentioned Dr Kiran Mazumdar Shaw, chairman and managing director, Biocon during her talk at the BIRAC's Foundation day at Delhi. "They should stop India bashing as it won't help in any way" she said. Dr Shaw requested the prime minister's office to have more thrust on science and technology. She added further, "Manufacturing requires public private partnership to develop highest quality product at low cost. That can't be done unless there are interventions at highest level."

Knocking opportunities: Do we fit into competitive space?

With several biologics off the rack of patent shelves in the next five years, the combined sales potential of more than US$ 60 billion represents a massive opportunity for India to contribute through vaccines and biosimilars.

To lap this up, there is a need to build a strong image globally, believes Prof Anurag S Rathore, Department of Chemical Engineering, Indian Institute of Technology (IIT), Delhi. "One or two incidents on quality are repeated globally, leading to negative perceptions," he says, "Need to do more to change this as a country. Action should be taken against the bad products. There are three aspects: technical, policy and brand management that require attention."

Talking in particular about vaccine industry's role, Dr Suresh Jadhav, executive director, Serum Institute of India, drew a comparative scenario between developed countries and India. "Two third children across world getting Indian manufactured vaccines. While in US, there are Pfizer and Merck, the Europe has few manufacturers that include GSK and Bethovan are few others. Therefore, the role of 52 Indian vaccines manufacturers whose 23 products have been so far certified by WHO, obviously becomes stronger. Also, at times, GAVI used to procure pentavalent vaccine at $4 but now with manufacturers from developing countries in picture, the prices have come down to $1.5." Dr Jadhav wants the government to understand the issues not just politically but financially as well. He adds,

"We admire government's political will but the allocations are not enough to implement vaccines in universal immunization programme."

Raising an important issue, a top executive from Shantha Biotechnics, says, "It is very important to bring down the cost of vials as the product inside them is far lesser in cost then the vials itself. Packaging material cost woes have to be addressed to bring a sea change in affordability."

Undoubtedly, the quality and affordability are two factors that can make or break the backbone of an industry. Infact, the quality is said to be the holy grail of manufacturing. Therefore, pointing towards importance of sustainability, Dr Amulya Panda, senior scientist, National Institute of Immunology (NII) reminds about the failure of antibiotic vaccine manufacturing in past and a need to study the causes. "The unemployment is a huge issue and how can biomanufacturing help to reduce that must be our goal. We need to build our own capacities and capabilities. Have to convince government that biotech products are not comparable with other general products."

Mr Vinay Konaje, managing director, Navya Biologicals, feels that India has only fewer options than to jump into manufacturing bandwagon. "There is no doubt that in future, the biomanufacturing will have to cater to huge population and meet demands," he says.

What is holding us back?

The competency has a lot to do with the next stage. So has the industry as well as government got their priorities right for that? Infact, the question is whether the existing system being followed is indeed the right one? Therefore, as one of the right approaches, national and international partnerships are very important for reducing risks during product development and increased capabilities. The scientific tourism as rightly pointed out by an industry leader can be a great plus point for the country only when we ensure the world class facilities at much affordable cost.

"Government has been both a challenge as well as a partner," says Mr Shrikumar Suryanarayan, founder, Sea6 Energy, who calls the existing regulatory laws as xenophobic. "Biodiversity law says you need to take permission from the government virtually. See a phenomenal shift in attitude for innovation that never existed earlier. Cutting across verticals, I envision an industry that has proactive regulations."

The regulations instead of ensuring quality have become a bottleneck for innovation, feels Dr Shirshendu Mukherjee, senior strategic advisor-India, Wellcome Trust, adding, "There is a need for rejig at policy level. Advocacy has to be generated for implementing the innovations. Cutting across verticals, I envision an industry that has a proactive regulation."

Given their defunct status, it is easier to work with NASA but not Indian public institutes, said a highly agitated industry expert. "Every FDA, be it Europe or US, has the right to protect their subjects. We use technology for creating customized products. End user perspectives need to be considered," he adds further.

Ms Mukta Arora, director, Global External R&D, Eli Lilly India lays the thrust on predictable regulatory regime. Obsolete ideas must be replaced with new approach she says adding that algorithms or data on the disease is missing. Innovation has to be in sync with the policy framework."

Making the right pitch for inter-ministerial interactions, Dr K Vijay Raghavan, secretary, DBT, feels that the communication is missing. "Need to chart out exact estimate of what our true expectations are! And efforts have to be driven collectively at higher levels." Agrees Dr T S Rao, senior advisor, DBT, who says that the great vaccine programmes we see today would have not been possible if there would have not been communication. "I am a strong supporter of Make in India but we have to know our exact requirement and the effort should be driven by collective effort of departments and ministries."

Local ecosystem has to be leveraged

The missing link between various components of a regional ecosystem, serves as a hindrance to overall growth of the sector. For example, as pointed out by an expert, despite hosting one of the largest bioindustrial company and largest vaccine firm, the city of Pune has yet not been able to leverage it for presenting itself as a potential hub.

Mr Shomitro Ghosh, CEO, WISH Foundation (involved in promoting healthcare innovations), gives an interesting perspective

based on experiences. He says, "The 80 percent of innovators are from South India whereas 70 percent of requirements are form North India. In such situation, language and other barriers are a great hindrance to effective implementation. Need is to have local innovators." On policies, he adds,"Despite a national policy, the actions at state level are missing. Private sector is forced to be a part of government schemes for the sake of it. There has to be a crosstalk before any big policy is devised and implemented."

The lack of connect between existing ecosystems and the biotech enterprises can lead to hurdles in successful product development. The accessibility to the business and technical platforms is another factor that influences the biotech landscape.

As per Ms Deeepanwita Chattopadhyay, chairman and CEO, IKP Knowledge Park, "Collaboration between academia and industry help in cost cutting, thus paving way for delivery of good technologies. Complimentary verticals are required for technology development."

The research institutes have to work within confines of limited financial and work resources. Prof S Ramaswamy, CEO, Centre for Cellular and Molecular Platforms (C-CAMP) mentions, "We don't have enough disruptive technologies as the budget is just 100 fold whereas the biologists are 1000 fold."

Sharing his experiences on do's and don'ts, Dr P M Murali, president, Association of Biotechnology Led Enterprises (ABLE), says, "Have done partnerships with the academia and learned that we have to be careful about biocluster environment. Keeping a University just as a supply chain model has to be done away with."

For building the indigenous product manufacturing movement in the industry, we have to set our house in order. And that surely can't be achieved through one component working overtime while others still figuring out their exact role. There is need for seniors from industry to understand the needs of budding entrepreneurs and mentor them without a feeling of competition. Therefore, to understand the context in which we are working has to remain on top.

Overcoming barriers:

âˆ? Lack of infrastructure.

âˆ? Unskilled workforce.

âˆ? Not enough translational research.

âˆ? Regulatory issues.

âˆ? Missing local ecosystem

Factors that could serve as catalysts :

â‡“ Development of local regional hubs.

â‡“ Pubic private partnerships.

â‡“ Leveraging academic expertise.

â‡“ Policies in sync with industry's needs.

â‡“ Incentivizing technology entrepreneurs.

(Note: The article is based on the panel discussions at BIRAC's Foundation Day and personal interactions.)