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Investing in Biopharma can improve access to life-saving medicines

01 March 2022 | Views

In the last few decades, the pharmaceutical industry has been expanding its reach; a PwC study had anticipatedthat by 2018, over 30 per cent of global pharmaceutical sales would stem from emerging markets. Another research indicated that from 2015-2020, emerging markets' expenditure on medicines was supposed to touch $190 billion in sales growth, while Africa alone registered industry expansion to $20.8 billion in 2013 from $4.7 billion in 2003. These figures are clearly indicative of the soaring demand for pharma's (hence bio-pharma's) supply, which is growing exponentially and becoming increasingly pressing with every passing year

This is a challenging issue, because while access to quality medical products improves health conditions and saves lives, one-third of the world's population lacks timely access to it. Studies suggest that at least 10 per cent of drugs on third-world and second-world nations' shelves are substandard or spurious. Regulatory authorities combating substandard remedies and promoting quality ones find their efforts insufficient.

Implement value-added regulatory practices

One way to combat issues of lack and promote availability of necessary quality medicines is by applying value-added regulatory practices and utilising available resources such as by convergence and reliance initiatives.

Shaping new markets is dependent on collaborative efforts between industries such as pharma and food, a path also known as industry convergence. Merging of these industries has resulted in the medical nutrition industry. Following knowledge diffusion and consolidation, subsequent efforts are based on technological convergence. While medical nutrition's core

domain remains food, its technological development is driven chiefly by pharma advancements. Hence, the success of this nascent sector is completely dependent on the degree of convergence of its parent industries.

Simultaneously, each parent market has to continue to focus on its own path and initiatives as an entity while converging on the side. Only in this fashion, can it persist in its own relevance and continue to contribute as required to other sectors. By being self-reliant and continuing its self-growth, will industries be equipped to drive newer industries.

Collaborative R&D ecosystem for Biopharma

In any environment, a collaborative habitat could spell the difference between success and failure, and India's R&D ecosystem has always registered a mixed performance. And yet, it managed to respond extremely well to COVID-19, as indicated by over 72 per cent of respondents in the Global Biopharma Resilience Index conducted by global industry enabler Cytiva. They also indicated a satisfying R&D collaborative environment, with the country ranking a healthy 8th on this particular indicator. The study by Cytiva identified collaboration as the unusual catalyst to this remarkable triumph.

With research scientists present through initial stages and clinical trials alongside regulators setting the rules for commercialisation, biopharma is undergoing vast changes right from its initial development processes. Even that can't explain the rare kind of R&D collaboration in the last year in the race to end the pandemic. During the COVID-19 Vaccines Global Access (COVAX) initiative, aimed at ensuring equal access to vaccines, 190 nations converged to expedite the immunisation drive. In a unique step, competing industry operators too set aside differences to collaborate on the key challenge.

If this unique first continues to be a predominant factor in the industry, it could forge unmatched continual momentum and build a vibrant R&D environment going forward. And this new approach could possibly remedy the challenges faced by the R&D arena.

Supply chain resilience

At present, the industry has consolidated its efforts to combat the COVID-19 pandemic with extraordinary drive and speed, with an acute supply chain focus. But there are some tough challenges. The industry has progressively strengthened its global supply chain capabilities for the manufacturing and distribution of drugs, thus driving cost efficiencies through economies of scale. On the flip side, this may cause it to be subject to supply bottlenecks at times. In the case of certain poor countries, these bottlenecks led to shortages of essential drugs such as oncology biologics are quite regular occurrences.

Experts believe the industry is in a phase of super globalisation and may need to tweak its supply chain a little to help ease such bottlenecks. It could consider building sturdier supplier networks across the world and perhaps fortify domestic production, as well as invest in improving the industry's response agility to other trials.

Another challenge has been the burgeoning presence of spurious and substandard drugs in the supply chain. The industry has to involve national and international regulators in this grave matter so that the issue can be tackled with the gravitas that it demands.

Strengthen capacity building networks

The biopharma industry has realised that a great way to meet targets is by involving home-grown talent and leveraging their knowledge, network and channels. In fact, 65 per cent of executives believe pursuing policies that actively encourage domestic R&D and manufacturing could be a great response to the whole crisis, and the governments are also prioritising the same.

The question of manufacturing agility

The pandemic has once again put the spotlight on a relevant but much ignored factor in biopharma, and that's manufacturing agility. Being able to produce the necessary quantum of drugs at the relevant speed was crucial, and the industry responded with uncharacteristic speed. While high-income countries did perform extremely well, even India proved that we could keep pace.

There are still challenges to face in this sphere, since domestic companies doubt their capacity to be able to meet their own nation's needs for several medicines. For example, even when it comes to essential vaccines and insulin, respondents believed their capacity was only to be able to meet about 75 per cent of total local needs if the demand arose.

One of the main reasons cited for the same is a lack of suppliers' agility. In order to cure this lack, transforming the entire manufacturing process is necessary; as is employing innovative technologies in order to expedite drug development and manufacturing. Only upon shifting biopharma's manufacturing gears into the fast lane can be truly prepared.

Change in government policies

Policymakers everywhere are recognising the value of home-grown R&D and manufacturing, especially of drugs. Governments are coming up in support of local production and encouraging regulators to support the industry's commercial imperatives by way of lenient trade and tax policies. In fact, in the Cytiva study, two-thirds of executives responded in the affirmative about their local laws being helpful in development and manufacture of new drugs.

However, now is the time for regulators to go beyond simple policy formulation. Public and private funding of startups is extremely necessary, and should feature in the policies. The pandemic has already showcased how regulators and companies can collaborate on common grounds—this lesson has to be applied overall, to support every relevant idea's journey from the lab to markets via the evolved models that have been created during the pandemic.

Harmonisation of regulatory systems as one unit is a great initiative, leading to the hope that one day a "global, uniform regulatory system" could finally be forged. A common set of technical rules makes the path easy for organisations to follow as well as an easy approval window, if not a unified global one.

The future of Biopharma

Biopharma is an industry of the future. At present, it's dependent on many factors and contingencies to succeed and be relevant. This study shows the areas in which a little support to this industry can pay back in a big way.

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