

Pharma industry must turn more innovative

To go beyond generics, the industry needs policy support by way of R&D tax breaks, patent law tweaks and research talent

NILESH GUPTA

Perhaps the most profound Harry Potter quote is: "It is our choices that show what we truly are, far more than our abilities." The Indian pharma industry is a product of the choices made by the founders that created it; people like Yusuf Hamied, Anji Reddy and Desh Bandhu Gupta. These choices made India the pharmacy for the world.

The Indian pharma industry operates at scale, and we are leaders in the global generic world. The Indian pharmaceutical market is estimated at \$40 billion and pharma companies export another \$20 billion. However, this is a miniscule portion of the \$1.27-trillion global pharmaceutical market. India ranks third worldwide for pharmaceutical production by volume, but only 14th by value. While our global generic position is a matter of pride, India is only the 12th largest exporter of medical goods. We have more than 30 per cent share in the global generic market but less than 1 per cent share in the new molecular entity space.

We have built scale and dominated in the pool we play in. It is now time to play at scale in a much bigger pool. To quote another Harry Potter line, Dumbledore says, "It

matters not what someone is born as, but what they grow to be." If we make the right choices, and if nurtured right, we can grow to be leaders in the global pharmaceutical market. The next story of the Indian pharma industry has to be one centred around innovation.

India playing at scale in the innovation space will not just help the country but will create a source of sustainable revenues, bringing new solutions to unmet healthcare needs. In India, this would lead to reduction in disease burden (development of drugs for India-specific concerns like tuberculosis and leprosy does not get global attention), creation of new high-skilled jobs, and probably around \$10 billion of additional exports from 2030.

Through the Covid pandemic, words that were not a part of regular parlance are in use now — quarantine, social distancing, the new normal; one word that has been over-used is innovation. Changing perspective and increasing the use of technology were the need of the hour. But now it is essential that innovation is at the core of business, and there is a dire need to embrace it if India wants to continue to be of relevance in the global pharmaceutical space.

Countries like China have already leapfrogged ahead, skipping the



Pharma firms need to scale up

generic chapter altogether.

For innovation to thrive in India, multiple challenges must be overcome: Complex and protracted approval processes (nod for development of new drugs in India takes 33-63 months versus 11-18 months in developed countries); lack of robust process guidelines (Indian websites list 24 guidelines compared to over 600 at the USFDA); lack of transparency (the US has an established pre-submission process and a time bound stage-gate process); inadequate capacity/capability (there are considerable enhancements needed across regulatory bodies in India); limited governance (Indian authorities currently only track the number of applications and approvals); and a

limited innovation mindset (we are risk averse compared to most global bodies, for example in the approval of clinical trials).

Key building blocks

Five key building blocks need to be in place for India to build a sustainable innovation story:

One, an enabling regulatory structure with simplified processes, robust guidelines, predictability, increased capacity and strong governance. India needs a 60 per cent reduction in the approval timeline to be competitive.

Two, robust funding support with government aid for industry investment through policies/incentives, direct government investment, and significant PE/VC investment. Countries vie for innovation dollars and India has to offer an attractive set of benefits — weighted R&D deduction, additional patent box benefits, and progressive policies to increase innovation funding are a must.

Three, strong linkages between academia and industry with high quality academic talent and infrastructure, industry-oriented research, and strong governance. The US created the Bayh-Dole Act encouraging academics to set up independent companies. India needs world-class centres of excellence to

attract global talent and support cutting-edge research.

Four, a favourable policy landscape through coherent policies across research, technology commercialisation and IP.

And, five, innovation hubs to accelerate collaboration. We need several at-scale innovation hubs co-locating academia, public R&D centres, industry, start-ups and incubators.

The Indian Pharmaceutical Alliance has submitted a report detailing each of these.

The innovation vision is to create and develop breakthrough products that will allow Indian pharma companies have a dominant global presence. One factor that has already helped the pharma industry is the 'Make in India' campaign. The government has set aside investments and funding to make the industry more self-reliant. We now need to truly put our minds and money together to realise this different, bigger, more relevant vision.

To quote from the *Gita*, "We are kept from our goals, not by obstacles, but by a clear path to a lesser goal." The lesser goal has been achieved. It is now time to reach for the higher goal.

The writer is Managing Director, Lupin