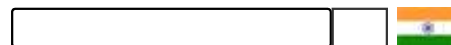


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It has been a long journey for the Indian pharmaceutical industry from being merely an import dependent to emerging as a self-reliant producer and now as one of the main export countries in the global market. Today the Indian pharmaceutical industry is the world's third largest by volume and worth over \$42 billion. Let's chart the future of this 'sunrise' sector as it stands presently



India exports pharmaceuticals to approximately 206 destinations with the US being the largest export destination followed by Africa and Europe. It is a leader in vaccine manufacturing and supplies over 60 per cent of global vaccine demand. With an export value of \$24.44 billion (2020-21), the products of the Indian pharmaceutical industry continue

to improve health outcomes for patients worldwide. The policy initiatives by the Government of India and entrepreneurship spirit of Indian industry have made it possible to achieve this.

In the recent Union Budget 2022, the Government of India recognised the pharmaceutical industry in the sunrise sector of the economy which is expected to register a threefold growth in the next decade. According to the Indian Economic Survey 2021-2022, the pharmaceutical industry is estimated to reach \$65 billion by 2024. The industry aspires to grow to \$120-130 billion by 2030. For this, the industry can embark on a vision of establishing India's global leadership in life sciences, while driving deeper domestic access and affordability.

Mettle of Indian pharma industry

"Crisis doesn't create character, it reveals it". The pandemic posed unprecedented and new challenges but it also offered opportunities and learning to the Indian pharma industry. The pandemic demonstrated the pharma industry's commitment to be a reliable supplier of high-quality, affordable medicines.

The urgency to understand the virus and develop new medicines and vaccines provided unparalleled learning opportunities. In India, the industry not only supplied medicines continuously but also contributed to preventive healthcare, sanitation and quarantine facilities. It responded to the challenges of COVID-19 by evaluating the possible utilisation of available drugs (repurposing drugs) and exploring innovative approaches to fight the pandemic. This coupled with regulatory reforms, initiated by the Central Drugs Standard Control Organization (CDSCO), has resulted in speedy permissions for clinical trials, and encouraged approval of applications to manufacture or import drugs and vaccines for trials.

Over the last two years, collaboration and coordination between government, industry and other stakeholders was instrumental to address challenges collectively by sharing best practices, knowledge, technology, and experiences.

Several Indian companies forged strategic alliances with global pharma to provide better access to essential drugs/new treatments for COVID-19 such as Remdesivir, Molnupiravir among others. Under the initiative of Vaccine Maitri, the Indian government delivered over 14.68 crores of doses of vaccine to 97 countries. A new trend of joint development of vaccines by private entrepreneurs and government laboratories has also been witnessed. For example, Bharat Biotech in collaboration with Indian Council for Medical Research (ICMR) and National Institute of Virology (NIV) manufactured COVAXIN vaccine.

Advantage India

Under the ambit of 'Ease of Doing Business', the Government of India took initiatives to reduce the compliance burden and amended the Drug Rules. Further Policy support such as the Production Linked Incentive (PLI) scheme for Key Starting Materials (KSMs)/ Drug Intermediates, Active Pharmaceutical Ingredients (APIs) and other pharma products by the government announced in 2021, is a positive and significant step towards promoting domestic manufacturing thereby increasing not only self-reliance but also cater to the Make in India pharma products for the world.

India has the advantage of both scale and reach from the pharmaceutical sector perspective. The cost of manufacturing pharmaceutical goods in India is relatively lower than advanced countries. India has a highly skilled workforce and enjoys price advantage over other developed nations while providing best of quality medicines.

Leading the post-pandemic world

Having contributed significantly to the generics, the industry is now poised to expand its innovation and research and development (R&D) capabilities to offer cutting-edge products at affordable prices. It is time to move from 'Make in India' to 'Discover and Make in India'. The thrust would be on accelerating R&D and innovation, smart manufacturing,

foster policy reforms, expedite digital transformation, and nurture valuable collaborations.

Focus on R&D and innovation: Indian pharmaceutical industry would need to move up the value chain and focus on innovation which accounts for 2/3rd of the global pharmaceutical market size. The Indian pharmaceutical industry needs to build a strong innovation pipeline (with 5-7 new molecular entities and 10–12 innovation launches per year by 2047). Towards this, the industry is now venturing into complex generics and specialised drugs. Idea is to enhance Indian pharma's significance in biologics, new drug development and innovations and on enhancing capabilities in biological sciences, usage of Information Technology, Cell and Gene therapy, all focused on patient needs.

Foster policy reforms: A fundamental enabler for a vibrant innovation ecosystem is a strong and efficient regulatory setup e.g., having a 'single window system', elimination of multiple regulatory bodies, establishing detailed guidelines. Learning from the pandemic, it is critical to ensure that there is an ongoing dialogue between the regulator and the industry for example - pre-approval meetings, more frequent industry meets, rolling reviews, may be considered.

Digital transformation: Digital transformation is imperative for improved patient care, cost-effectiveness, greater transparency, improved production, and drug development. Supply chains are also becoming more patient-centric due to the increased adoption of digital tools, telehealth, and app-based ecosystems. Latest technologies, like AR/VR, artificial intelligence (AI), machine learning (ML), 3D printing and additive manufacturing are assisting pharma companies to step up the research and development process, conducting tests in increasingly less time and adding newness to the products as well as improving efficiencies and compliance in manufacturing.

Nurture valuable collaborations: During COVID 19 pandemic, cohesive collaboration between the government, academia, and industry to promote research initiatives has been the key. Regular feedback, integrated efforts, sharing and consistent dialogue between industry stakeholders and government authorities has worked well during COVID-19 pandemic and this dialogue should continue in future too.

Focus on exports: Going forward it will be critical for the industry to consolidate the existing large export markets and to explore new ones. Indian missions abroad could be great facilitators in this context. At the same time, the policies in India would need to focus on supporting the industry to be competitive in the export market through policy instruments such as Remission of Duties and Taxes on Exported Products (RoDTEP), PLIs, incentivising R&D and innovation in the pharma sector.

The road ahead

India has an advantage of technology and world-class manufacturing capabilities that have been built over the years. This strength is critical in regulated and science driven industry as the rate of change is expected to be faster for the next two decades. Agility to adapt will be crucial in sustaining the competition. Indian industry has demonstrated its commitment towards patient welfare especially during the pandemic and will continue to do so in future too. Nonetheless, in this mission of providing quality medicines at affordable prices, the key will be to be a leader in technology and to leverage the demographic advantage of India and become the life sciences hub.

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