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K Raja Bhanu has been elevated from Executive Director to Director General of the Pharmaceuticals Export Promotion Council of India (Pharmexcil), effective July 1, 2024. Bhanu brings a wealth of experience from his distinguished career in drug control and regulation. He has a proven track record in advancing drug quality, safety, and regulatory compliance. His leadership at the Drug Control Administration (DCA) was marked by significant initiatives that enhanced drug regulation standards and reinforced India's pharmaceutical reputation globally. In his current role, Bhanu is set to drive the expansion of India's pharmaceutical exports, boost global competitiveness, and adeptly navigate the complexities of international regulations, leveraging his extensive expertise to foster industry growth and global prominence. In an interaction with BioSpectrum, he shared his plans on addressing many challenges before the Indian pharma industry to stay compliant with international regulations.



How do you feel after being appointed as Director General at Pharmexcil and what are your priorities?

I am truly honoured to assume the role of Director General of Pharmexcil. I am grateful to all the industry stakeholders and the government for their trust in my leadership. This position is a significant responsibility, and I am committed to addressing the key challenges facing the pharmaceutical export sector. Building on the successful initiatives of my predecessors, my priorities will include identifying and understanding these challenges, engaging regularly with industry leaders to address their concerns, and representing their interests to both state and central governments, as well as international agencies, to achieve effective solutions.

Could you provide an overview of the current export scenario of Indian pharmaceuticals in the global markets?

India’s pharmaceutical sector has experienced significant growth in recent years, with the country now exporting medicines to over 190 nations. By the end of April 2024, pharmaceutical exports had reached $27.9 billion. In the last quarter alone, we saw a growth rate exceeding 9.6 per cent, and we expect this figure to hit double digits by year-end. This growth highlights India's expanding ability to meet global healthcare needs through affordable generic drugs.

When comparing India’s exports to global market trends, our sector is thriving. In the calendar year 2022-23, the global pharmaceutical market had a turnover of $1,407 billion with just a 1 per cent growth. In contrast, India’s pharmaceutical exports grew by over 3.25 per cent during the same period, reaching $25.394 billion. This growth accelerated in the following year (2023-24), reaching $27.9 billion.
Overall, India’s drug and pharmaceutical exports increased by 7.36 per cent, rising from $2.26 billion in April 2023 to $2.43 billion in April 2024. Key exporters from India include prominent companies such as Dr. Reddy’s Laboratories, Elkos Healthcare, Aurobindo, Cipla, Lupin, and Sun Pharmaceuticals, among others.

What is India's share in the global pharmaceutical export market and which are the major markets where India is growing?

India holds a 5.71 per cent share of the global pharmaceutical export market. The major portion of its exports comprises formulations and biologics, accounting for 72.54 per cent of the total, with drug intermediates and bulk drugs following. For

FY24 (up to February 2024), India's pharmaceutical exports totalled $25.02 billion, compared to $25.4 billion in FY23 and $24.59 billion in FY22. The key export destinations are the USA, Belgium, South Africa, the UK, and Brazil. India has the highest number of US FDA-compliant companies with facilities outside the USA, houses about eight of the top 20 global generic companies, and directs over 55 per cent of its exports to highly regulated markets. Additionally, India is the largest global vaccine exporter, meeting approximately 65-70 per cent of the World Health Organization’s vaccine needs.

Which initiatives have Pharmexcil undertaken to promote pharmaceutical exports from India? How do these initiatives facilitate Indian companies' entry into global markets?

Pharmexcil has been actively working to enhance the global presence of Indian pharmaceutical companies. We have launched several initiatives, including trade fairs, buyer-seller meets, and promotional campaigns in key markets. These activities help Indian companies understand international market demands and regulatory requirements, facilitating smoother entry into global markets.

What are the key regulatory challenges Indian pharmaceutical companies face globally? How is India addressing these challenges to stay compliant with international regulations?

Indian pharmaceutical companies face several regulatory challenges, including compliance with varying international standards and frequent updates to regulations. To address these challenges, India is continuously updating its regulatory framework and ensuring that domestic companies adhere to international standards. The implementation of stringent regulations and regular training programmes for industry professionals are steps taken to stay compliant.
Apart from helping companies navigate complex global regulatory requirements, we are also giving **the** highest priority in addressing concerns related to quality and safety. Pharmexcil is actively involved in overcoming these challenges by organising awareness campaigns, providing industry training, and facilitating dialogue between regulatory bodies and pharmaceutical companies. Our goal is to ensure that Indian pharmaceutical products meet the highest standards globally.

In what ways is India upgrading its pharmaceutical industry to align with global regulatory standards?

India is making significant strides to align its pharmaceutical industry with global standards. Recent improvements include the overhaul of regulatory frameworks such as Schedule M, which mandates rigorous quality and safety standards. The central government has also introduced regulatory reforms aimed at enhancing production practices and environmental compliance, ensuring that Indian pharmaceutical products meet international benchmarks.

How is India faring in the Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs) sector?

The API sector remains a challenging area for India. Currently, we rely on imports for more than 80 per cent of intermediates and KSMs, primarily from countries like China. However, there is a strong push towards achieving self-sufficiency. The government’s Production-Linked Incentive (PLI) scheme is designed to boost domestic production and reduce dependence on imports, which we hope will significantly enhance our capabilities in the API sector.

How do the PLI scheme and other government initiatives contribute to the improvement of the pharmaceutical sector in India?

The PLI scheme is a crucial initiative aimed at enhancing the domestic production of APIs and other pharmaceutical products. It offers incentives to both domestic and international players to invest in India, thereby boosting our production capabilities and reducing import dependence. This scheme, along with other government initiatives, provides significant financial support and encourages technological advancements, contributing to the overall growth and competitiveness of the Indian pharmaceutical sector.

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