

Ravi Uday Bhaskar - Director General, Pharmexcil, India



Despite global economic challenges, [India's pharmaceutical sector] has demonstrated robustness... We are determined to leverage this momentum

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Pharmexcil's Ravi Uday Bhaskar discusses how Indian pharma is rebuilding global confidence in its exports via a focus on quality, expanding into high-potential new markets like those in Latin America, and adapting to global trends like the US Inflation Reduction Act and changing European regulations.

As the Director General of the Pharmaceuticals Export Promotion Council of India (Pharmexcil), could you provide insights into Pharmexcil's current mission and priorities?

Pharmexcil mission centers around promoting pharmaceutical and allied products exports from India. Our foremost priority at this moment is to rebuild confidence among global regulators and markets, particularly addressing recent incidents related to substances like ethylene glycol & Diethylene Glycol and to instill the Quality culture among our member companies.

In the wake of a robust seven percent economic growth in the country, our focus includes expanding exports to untapped markets specially Latin America, a region with immense potential. Despite Africa being a crucial export destination next to North America & EU, we recognize the untapped opportunities in Latin America. Our efforts, including leading delegations and collaborating with Indian missions, have shown promise. With an eight percent growth recorded in the last financial year, we are determined to leverage this momentum and further penetrate the

Latin American market. In February, our delegation will explore additional countries in Latin America, solidifying our commitment to enhancing pharmaceutical exports from India.

Could you shed light on the current policies shaping pharmaceutical exports from India?

Pharmexcil is actively engaged in promoting pharmaceutical exports from India through strategic initiatives. One notable effort is the Global Regulators Conclave, where 75 regulators from 50 countries convened to discuss post-COVID changes in regulatory frameworks. The objective is to foster convergence, akin to mutual recognition agreements seen in the US and Europe, aligning India with countries of similar regulatory standards. The recent signing of agreements, such as the one with the UAE & Australia, facilitates the fast-tracking of products from Indian companies with stringent regulatory approvals.

Moreover, India is actively pursuing flexible free trade agreements, aiming to streamline movement and reduce timelines for pharmaceutical exports. The country, home to the highest number of US FDA-approved sites outside the US, seeks global recognition of its facilities to further ease export processes.

The Product Linked Incentive (PLI) scheme is a pivotal step in reducing import dependence, specifically on active pharmaceutical ingredients (APIs) and starting materials, notably from China. Pharmexcil, in collaboration with the Ministry of Commerce and Industry, conducted a comprehensive study identifying products heavily reliant on Chinese imports, forming the basis for the PLI scheme. The scheme's implementation is expected to play a crucial role in reshaping India's import landscape.

Additionally, the Indian government's commitment to funding research and development in the pharmaceutical sector reflects a forward-looking approach. Recognizing the importance of research and innovation, especially considering the changing dynamics of the industry, the government has allocated funds to encourage collaboration with premier research institutions in India. This dual focus on reducing import dependence and fostering innovation positions India for sustained growth in the global pharmaceutical landscape.

How do you perceive India's readiness to transition from a volume-based to a value-based pharmaceutical landscape? What distinguishes the current emphasis on research and development, particularly in active pharmaceutical ingredients and fermentation

technology?

India is undergoing a transformative shift from a volume-based to a value-based pharmaceutical landscape, particularly evident in the emphasis on biosimilar and complex generics. Major players, recognizing the importance of innovation, are strategically venturing into areas such as biosimilar. Biocon's acquisition of Viartis and India's approval of 98 biosimilar highlight the industry's commitment to exploring new frontiers.

The urgency to diversify beyond conventional generic drugs stems from a collective realization that future market leadership requires a focus on biosimilar, complex generics, and Cell & gene therapies as well as the development of active pharmaceutical ingredients (APIs). Notably, fermentation technology has emerged as a critical area of focus, especially in the context of Self Reliance for APIs.

The response to the pandemic showcased India's capability to swiftly adapt and innovate. India's prowess in the vaccine industry is exemplified by the rapid development and distribution of COVID-19 vaccines, (such as Covaxin). The indigenous development of Covaxin, in collaboration with the National Institute of Virology and ICMR, attests to India's research and innovation capabilities. Distributing 300 million doses to 101 countries underscored India's commitment to global public health and reinforced its position as a significant player in the pharmaceutical landscape.

This strategic shift towards innovation, coupled with demonstrated success in responding to global health crises, positions India on a trajectory towards becoming a value-driven force in the pharmaceutical industry. The integration of research and development across various domains, including biosimilar, complex generics, and fermentation technology, signals a promising future for India in the global pharmaceutical landscape.

How are Indian pharmaceutical companies, particularly those associated with Pharmexcil, responding to and navigating challenges posed by global trends like the Inflation Reduction Act and changing European regulations, considering that up to 90 percent of some companies' total production is exported?

The US market remains a cornerstone for Indian pharmaceutical exports, constituting around 30 percent of the total. Many Pharmexcil-affiliated companies, exporting substantial portions of their production, often up to 90 percent, prioritize the US market due to its favorable pricing and the recognition of facilities with US FDA approval. Despite discussions around global trends, including the Inflation Reduction Act and changing European regulations necessitating price negotiations, Indian companies view the US market as pivotal.

While acknowledging price pressures, the industry's volumes and exports continue to show resilience. The US, with its drug shortages, provides a conducive environment for Indian companies. Notably, 48 percent of the New Drug Applications (NDAs) in the US originate from India, offering substantial opportunities for exploration and growth in the US pharmaceutical market.

The prevailing sentiment among Pharmexcil members indicates that, despite regulatory changes and challenges, the US market remains a critical growth driver for Indian pharmaceutical exports. The industry's ability to navigate evolving regulations while sustaining positive growth underscores its adaptability and strategic approach in addressing global trends.

Why has Pharmexcil identified Latin America as a significant opportunity, and what are the plans and expectations for the region in the upcoming year? How is Pharmexcil supporting and guiding companies entering these markets, and what insights can you provide regarding the challenges and opportunities in expanding pharmaceutical presence in Latin America?

Pharmexcil focus on Latin America stems from the region's rising interest and the substantial potential it presents for Indian pharmaceutical companies. The decision is grounded in the relative cost of production and drug prices in Latin America, which sometimes surpass those in Europe, making it an attractive market. Brazil, with an 11.13 percent growth recorded in the last financial year, stands out as a key export destination. The strategic move to diversify beyond the US and Europe reflects a broader expansion plan, recognizing the untapped opportunities in highly potential markets like Latin America and ASEAN.

Pharmexcil aims to facilitate this expansion by providing support to Indian companies entering these markets. The focus countries, including Mexico, Colombia, Chile, and Venezuela, present unique challenges due to their diverse and smaller markets, necessitating a robust and strategic market presence both for Pharmexcil and the manufacturers. The growth recorded in the financial year 23, with a 642.67-million-dollar export and an almost 11 percent growth rate, underscores the success of this strategic shift and the region's growing significance for Indian pharmaceutical exports.

How has Pharmexcil contributed to the success of Indian pharmaceutical exports, particularly in entering new markets and navigating international challenges? Can you

provide examples of the organization's impact, success stories, and the role it played during critical times, such as the COVID-19 pandemic?

Pharmexcil, in collaboration with the Ministry of Commerce, has been instrumental in supporting the pharmaceutical industry by organizing business meetings and providing funding through the Market Access Initiative. One notable initiative includes subsidizing 50 percent of registration charges, up to two crores Rupees (200 lakh or 20 million INR) per company per year, for manufacturers registering products outside India. Pharmexcil has played a pivotal role in creating platforms for manufacturers, fostering international exposure through exhibitions and delegation travels.

The organization works closely with Indian embassies, business chambers, and regulatory authorities, acting as a catalyst for addressing concerns and facilitating discussions, particularly in the context of free trade agreements. Pharmexcil's support extends to both small and large manufacturers, aiding them in navigating regulatory challenges and representing their interests.

During the COVID-19 pandemic, Pharmexcil demonstrated its essential role by sourcing and supplying medicines to different Latin American countries. The organization maintains regular communication with embassies and plays a crucial role in coordinating trade delegations to focus countries. Through initiatives like webinars, Pharmexcil ensures global outreach, fostering matchmaking opportunities between Indian and international regulators and companies. The organization's multifaceted approach has proven invaluable in promoting Indian pharmaceutical exports and facilitating global collaborations.

How is India addressing the issue of alignment of international regulatory standards? Is there a specific direction or ambition that India, its regulators, or the government is pursuing to enhance the alignment and facilitate pharmaceutical exports?

Currently, India operates as an observer of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Discussions within India are ongoing regarding potential alignment with ICH standards. Simultaneously, India is working on its own amendments to elevate regulatory standards, aligning them with stringent international authorities. While becoming a member of ICH or similar organizations might not directly impact pharmaceutical exports, the Indian government and regulators are actively engaged in formulating standards that adhere to global practices. Recent amendment of Schedule-M (Good Manufacturing Practice) is signaling a commitment to aligning with international regulatory expectations. This

initiative aims to boost confidence in Indian pharmaceutical products, reduce inspection requirements, and streamline regulatory approvals, thus supporting the growth of the Indian pharmaceutical industry on the global stage.

Looking ahead to the next year or two, what are your aspirations for the Indian healthcare and pharmaceutical sector, particularly in terms of exports?

In the coming years, I am optimistic about the Indian pharmaceutical sector's performance. Despite global economic challenges, the sector has demonstrated robustness. Last fiscal year, we achieved exports of 25.4 billion with 3.25 percent growth, and in the current fiscal year, we've already recorded 8.1 percent growth, exporting 20.38 billion in nine months. Notably, October saw an unprecedented 29 percent growth. This resilience is attributed to the global demand for affordable generics, with India being renowned for producing high-quality generics at cost-effective prices. The industry is also venturing into biosimilar, new chemical entities, and new biological entities, shaping the future landscape. I anticipate reaching 28 billion in exports this fiscal year with nearly a 10 percent growth rate, outpacing the global generics growth rate of 4-5 percent. This positive momentum instills confidence in the trajectory of the pharmaceutical sector in India.

Do you have a final message to share?

I'd like to emphasize that India has played a crucial role in supplying affordable drugs, contributing to the control or eradication of diseases like tuberculosis, malaria, and HIV worldwide. Even during the COVID-19 pandemic, India promptly met the pharmaceutical needs of various nations. While Pharmexcil is committed to promoting exports, we also focus on enhancing the capabilities of Indian exporters through capacity-building programs. It's imperative for pharmaceutical exporters to prioritize quality and efficacy, considering the significant impact their products have on millions of people.

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