Anil Matai – Director General, OPPI India

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At a transformational moment for Indian pharma, OPPI's Anil Matai outlines how the country's government is more receptive to innovation and action-oriented than ever before, how the industry is increasingly aligning with global standards to foster an innovation transition, and the importance of always bearing patiennt accessibility in mind in the Indian context.

In your current role, representing the multinational pharmaceutical industry in India and engaging with various stakeholders, especially the government, how do you perceive the current atmosphere? Are doors opening for collaborative initiatives, and what changes do you observe in the government's approach?

The present moment is pivotal for the industry, signifying an inflection point. The government's receptiveness and clear action orientation set a transformative tone. Unlike the past, there's a tangible momentum now. Historically, multinationals held a substantial market share until the mid-'70s, but the dynamics have reversed, bringing new challenges and opportunities. This juncture holds promise for regulatory improvements, addressing ambiguities, and fostering an environment conducive to multinational participation. The government's acknowledgment of issues like policies, pricing, and intellectual property protection signals a crucial shift. Recognizing that India's business share for multinationals is relatively small, there's a proactive effort to streamline complexities. This is vital for sustaining global companies' evolution in the Indian market, many of which have

significantly contributed to healthcare accessibility and affordability over the years. While access remains a challenge, collaboration with the government is deemed essential for addressing fundamental issues like healthcare infrastructure and medical education, emphasizing a holistic approach for sustained progress.

Given the broader industrial policy shift towards innovation post-COVID-19, especially in pharmaceuticals and biotechnology, how do you perceive India's position as a key player in these sectors?

India's role as the "pharmacy to the world" has been established for over two decades, serving as a major volume player in pharmaceuticals. The impact of COVID-19 seems to have catalyzed this existing strength. Notably, the swift and widespread vaccine rollout showcased India's capabilities on a global scale. The digitalization journey, evident in vaccine administration tracking, reflects a remarkable feat considering the country's infrastructure challenges. While India's democratic nature comes with inherent complexities, the response to the pandemic conveyed a strong message globally.

Despite persistent challenges, there is optimism for the industry's future. The messaging from the government indicates a positive shift, though it's acknowledged that there's still progress to be made. The industry is hopeful for better times ahead, emphasizing the need for tangible actions to complement the positive rhetoric and acknowledging that the needle is moving, albeit gradually.

Reflecting on the historical role of multinational companies in India, how would you describe the current landscape for OPPI members, especially considering your advocacy since joining? What are the key priorities, and where do concerns lie?

The current landscape for multinational companies associated with OPPI in India is characterized by three key priorities. Firstly, there's a continuous emphasis on the protection of intellectual property (IP). While the concept is not new, the focus is now on tightening the implementation to ensure robust IP protection. Secondly, a dedicated focus on quality standards has emerged. India, as a nation, faces perceptions related to quality and pricing competitiveness. Efforts are directed towards upgrading manufacturing facilities, enhancing skills, and fostering a quality-oriented mindset across the industry. The aim is to elevate India's reputation for producing high-quality pharmaceuticals. The third pillar centers around access to patients.

These three pillars collectively shape OPPI's priorities, addressing challenges and driving positive transformations in the industry.

How does the pharmaceutical industry tackle challenges in ensuring medicine accessibility, particularly in remote areas? How do you balance affordability and willingness to pay, given India's economic diversity?

Access to medicines in India involves a multifaceted approach, extending beyond regulatory approval. Our focus is on patient-centric strategies that go beyond geographical boundaries, aiming to bring medicines to underserved areas, including tier three and tier four cities or villages where infrastructure might be limited. Contrary to conventional challenges linked solely to affordability, we recognize that the willingness to pay plays a pivotal role. Despite the economic diversity in India,

with both billionaires and economically constrained individuals, the challenge lies not in affordability per se but in establishing mechanisms to ensure that medicines reach those who truly need them.

Our three key pillars, including intellectual property protection, quality standards, and access to patients, collectively shape our priorities. Furthermore, fostering innovation requires incentivization, especially considering the substantial investments and years spent bringing patented products to market. Regulating against unauthorized copying involves intricate regulatory policies and the need for streamlined communication between relevant government departments, addressing this linkage gap is vital for protecting innovation and ensuring a fair return on substantial investments in the pharmaceutical sector.

How can India's pharmaceutical industry foster disruptive innovation and align with global standards? what specific changes are crucial to ensure a swift shift towards a more global and innovation-driven regulatory approach?

India's pharmaceutical industry, often termed the "pharmacy of the world," is at an inflection point, recognizing the need for disruptive innovation to transition from volume to value. A pivotal factor in this transformation is the regulatory environment, and the recent appointment of the Drug Controller General of India (DCGI) with industry experience, signals a positive shift. However, to truly align with global standards and foster disruptive innovation, regulatory changes have to keep pace with the global best practices, promoting an environment conducive to disruptive innovation, and expediting decision-making. The recognition of India's innovation potential, as echoed by the Prime Minister's emphasis on science-led research, is a positive step. As we navigate this transformation, the ultimate goal is to attract global investments, instilling confidence among multinational companies that their intellectual property is secure and encouraging their commitment to India's dynamic pharmaceutical landscape.

What quick wins do you believe could capture the attention of headquarters and attract investments to India?

The realm of clinical trials and real-world evidence has positioned India as a strategic hub for global companies, driven by its vast patient pool, diverse talent, and disease prevalence. Over the past two decades, significant progress has been made in various domains, showcasing India's pivotal role. Key areas of advancement include clinical development analytics, regulatory affairs, and Clinical Trial Management, with several global companies establishing large-scale Global Capability Centers employing highly skilled professionals.

Notably, India has become a center for global commercial operations, particularly in clinical data sciences, where data analytics and processing contribute to real-time insights. The country actively engages in pre-marketing activities, safety surveillance, patient risk management, and safety data assessment. The ongoing investments and advancements not only underscore India's significance in global clinical trials but also highlight its role in shaping the future of patient safety monitoring and data-driven strategies, thereby solidifying its position as a key player in the global pharmaceutical landscape.

How can India achieve the ambitious $450 billion pharmaceutical market by 2047, considering key drivers like awareness, affordability, and lifestyle diseases?

The vision of a $450 billion pharmaceutical market in 2047 is indeed ambitious but within reach, given our GDP growth, which hovers around 6.5 percent to 7 percent. Historically, the pharmaceutical market tends to outpace GDP, often achieving growth rates about one and a half times higher. Remarkably, our aspiration stands at approximately 9 percent, an objective well within reach. Delving into the past decade, the pharmaceutical sector in India has demonstrated a commendable Compound Annual Growth Rate (CAGR) averaging around 10 percent . The numerical evidence firmly supports the viability of attaining our envisaged growth targets, given the historical growth rates and positive indicators like heightened awareness, increased affordability, and the rising prevalence of lifestyle-related diseases.

Achieving this goal necessitates a multifaceted approach, emphasizing crucial factors. Firstly, fostering innovation, especially in the realm of biotech and biologics, is paramount. While India possesses high intellectual capabilities, there is a need for significant progress in these areas. The focus should shift toward disruptive innovation, which demands a conducive regulatory environment to incentivize investments. Predictability in policies, including those related to price control, procurement, and product selection, is vital for creating an environment where investors can confidently make long-term commitments.

Intellectual property protection remains a cornerstone for attracting investments. India’s robust intellectual capital must be harnessed effectively, necessitating a proactive approach to protect innovations. Creating a regulatory environment that ensures predictability and aligns with global standards is instrumental in this regard.

Advocacy plays a pivotal role in influencing positive changes and expediting regulatory processes. Effectively communicating the industry’s needs, potential, and the urgency of streamlined regulations is key. It catalyzes regulatory bodies accustomed to traditional approaches, prompting them to adapt and expedite processes. This period marks a transition from mere discourse to concrete action, where regulatory bodies must be enabled to meet the evolving demands of the pharmaceutical landscape.

How crucial is the role of insurance and structured payment mechanisms in India’s healthcare system? Looking ahead to 2047, do you foresee a more formalized healthcare financing structure, and what essential steps are required to achieve this amid current challenges?

The absence of a single-payer system in India adds a layer of complexity to healthcare regulation, with everyone essentially acting as a payer. While the 2047 report didn’t explicitly address the dynamics of insurance and payers, it becomes evident that the role of insurance and structured payment mechanisms is crucial for the future of healthcare in India.

Currently, a significant portion of the population pays for healthcare from their own pockets, although there has been progress with the government rolling out general hospitalization coverage. The aim is to reduce self-pay incidents further, and by 2047, the objective is to have only 10 percent of the population relying on self-payment.

The challenge lies in evolving a more formalized healthcare financing structure. This involves not only increasing insurance coverage but also addressing fundamental questions about who will pay

and how to generate the necessary funds. While there have been steps taken in the right direction, such as raising awareness and engaging with stakeholders, achieving a more structured market requires a mindset shift.

To move towards a more formalized healthcare financing structure, there is a need for increased investment and attention to healthcare and education. This involves a two-fold approach: firstly, creating a conducive environment for insurance companies, encouraging private insurance, and building coalitions with stakeholders. Secondly, there is a need for a mindset change regarding taxation, with a focus on generating funds for healthcare through fair and inclusive means.

The journey toward a more structured healthcare financing system requires both patience and persistent efforts. While progress has been made, there is recognition that more needs to be done to create a system that ensures broader coverage and financial stability in the healthcare sector.

How is India strategically positioning itself for multinational pharmaceutical companies, especially amid evolving dynamics in the US and European markets?

In recent years, the pharmaceutical industry has witnessed a shift in focus towards emerging markets like India, especially with the challenges in established markets like the US and Europe. India has strategically positioned itself to attract multinational pharmaceutical companies by implementing initiatives like the production-linked incentive (PLI) schemes. For instance, the PLI schemes provide tax benefits to greenfield projects, encouraging local production and reducing dependence on imports, particularly for critical pharmaceutical components like active pharmaceutical ingredients (APIs).

Global companies are diversifying their supply chains and establishing manufacturing facilities in India. Backward integration is observed, with India reducing reliance on China for API imports and fostering domestic production.

In terms of market focus, multinational pharmaceutical companies are concentrating on super specialties in India. These include areas like oncology, virology, transplant, immunology, and other therapeutic segments with high complexity and technology barriers. These segments present opportunities for innovation and are less susceptible to easy replication, making them attractive for global companies.

For mass-market segments, which still constitute a significant portion of pharmaceutical sales in India, there is an anticipation that positive signals from regulators will drive global companies to refocus. Currently, there is a notable emphasis on super specialties due to their unique characteristics and the specific needs of patients in these therapeutic areas.

Overall, the evolving regulatory environment, coupled with initiatives to enhance domestic production and reduce import dependency, is reshaping the landscape for global pharmaceutical companies in India. The strategic focus on specialized therapeutic segments aligns with the complexities and demands of the Indian pharmaceutical market.

Do you have any concluding remarks to close the interview?

I remain optimistic about the pharmaceutical market in India. I believe the market will evolve, and there is potential for acceleration in the speed of positive changes. It’s crucial for global companies to actively engage in advocacy and establish partnerships with various stakeholders, including

academia, institutions, and regulators. The focus should be on fostering public-private partnerships to address the healthcare needs of the population. Ultimately, the goal is to improve the quality of life for patients across the country.

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