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The Indian pharma industry is very patient-centric, and all its changes ultimately strive to reduce prices, making medicines more affordable and accessible

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The IDMAâ??s Daara Patel outlines the associationâ??s role in representing the diverse voices of the Indian pharmaceutical sector, advocating for manufacturers of all sizes. He explores the challenges and initiatives around aligning with global standards, addressing issues like regulatory complexities and the shift towards biologics. Patel also uncovers the Indian industryâ??s efforts to reduce dependence on China for APIs as well as its commitment to quality, accessibility, and affordability of medicines worldwide amid evolving global pricing regulations.

Could you provide insight into what is the focus of the IDMA? Whose interests do you advocate for?

The IDMA represents the voice of the Indian pharmaceutical sector and was established in 1961 to support manufacturing in India by Indian manufacturers. Principally, we do not allow multinational companies as Principal members, though they can participate as associate members. We ensure that all members, including foreign manufacturers, are included in our meetings and receive weekly bulletins and other publications and correspondence.

The IDMA represents micro, small, medium, and large manufacturers, necessitating a balanced approach. We work closely with the government and have collaborated to organize sensitization workshops across India on the Revised Schedule M [a harmonisation of quality standards with

current global regulatory requirements â?? Ed.].

We implemented a phased program to ensure everyone is made aware of the changes. Presently, weâ??re working on revising GMP (Good Manufacturing Practice) to align with global WHO standards, particularly the basic need for essential medicines.

One notable aspect is IDMAâ??s structure, consisting of 20 specialized committees, headed by experts. These committees play a vital role in examining issues raised by our members or providing recommendations sought by the government, ensuring a thorough vetting process before submission.

20 years ago, there appeared to be challenges around regulatory alignment between the various states in India. Could you explain how this played out, and what steps have been taken to address this issue?

I wouldnâ??t describe it as misalignment, but rather a characteristic of any federal government. In a federal system, states have a significant degree of autonomy, while the central government is responsible for formulating policies. The effectiveness of these policies largely depends on the relationship between the centre and the states. Over time, the government recognized the need to standardize regulations across states. In the past, if one state had stringent regulations, businesses would relocate to a more lenient state to obtain licenses and operate. We are aligned with the governmentâ??s effort to harmonize regulations, promoting a consistent framework. This standardization is essential for the countryâ??s image.

Considering Indiaâ??s vast geographical area and the multitude of pharmaceutical manufacturers, what challenges have arisen in implementing regulatory standards, and how has this impacted the industry?

India indeed has a vast number of pharmaceutical manufacturers situated pan India, we have 3500 registered manufacturers and approximately 10,500+ manufacturing units that collectively produce over 60,000 different pharmaceutical formulations. Given the complexity and diversity of this industry, challenges are bound to arise. Itâ??s crucial to take a broader perspective and not hastily dismiss the complexities. The regulatory framework must consider this extensive pharmaceutical landscape. We must strike a balance between aligning with global standards and recognizing Indiaâ??s unique constraints as a developing nation. Our aim is to ensure that medicines are accessible to all, both domestically and internationally.

We endeavour to strike a balance considering our nationâ??s specific constraints. India isnâ??t as economically prosperous as developed countries, nor is it as advanced as some other developing nations or the Western world. We need to assess if our manufacturers can meet these rigorous global standards and for whom these medications are produced. Over time, weâ??ve come to understand that medicines should be accessible to all. Thereâ??s a common perception of double standards, where some assume thereâ??s one quality level for exports and another for domestic use. That isnâ??t feasible because the same machinery, resources, and skilled personnel are utilized in both cases. For instance, if a renowned company produces top-quality medicines globally, other companies must reach similar standards; otherwise, theyâ??ll be left behind. Itâ??s no longer just a market; itâ??s an arena where only the best and fittest survive. Itâ??s crucial for people to unite and harness synergies. We canâ??t have 10,000 foreign manufacturers indefinitely.

Is there reluctance among manufacturers to consolidate facilities?

While consolidations have been rare, it is an intelligent strategy for the industryâ??s advancement, bringing strengths together and supporting each other in manufacturing and marketing. Despite current reluctance, I am sure consolidation will happen in the future, as it has elsewhere in the world.

You mentioned the importance of getting certified by the WHO. Why is it crucial to have this basic WHO certification?

Having WHO certification alleviates concerns and reduces the need for multiple inspections. If WHO regulators meet our IPC or CDSCO officials, reviews our processes, and approves them, there shouldnâ??t be a need for additional inspections. The industry is evolving, and everyone should adapt, not just the manufacturers. Harmonization is the best way forward.

The crucial importance of vaccines has been one of the key lessons learned from COVID. Besides obtaining WHO approval, how can Indian manufacturers benefit from this newfound global importance?

There are faster turnarounds and quicker approvals now due to close and frequent coordination between all stakeholders. Approvals that used to take a long time can now be accelerated due to the lessons learned from COVID. Weâ??re confident that in case of an emergency, weâ??ve learned how to conduct accelerated trials. There wonâ??t be shortcuts, but the process will be quicker, more efficient, and more effective.

Shouldnâ??t your government ensure that Indiaâ??s regulator also has all the necessary international certifications, especially considering the substantial manufacturing in India?

IDMA recognized this issue 15 years ago and at the Pharmaceutical Analysts Convention, we focus on harmonizing different pharmacopoeias. We collaborate with the Indian Pharmacopoeia, US Pharmacopoeia, EDQM, MHRA, ANVISA from Brazil, among others. We aim to ensure that once you are IPC approved, you are at par with other regulators. However, some highly regulated market regulators tend to make changes and improvements which put us behind.

Looking at exports and Indiaâ??s global position, how are you preparing for the next wave of medicines, especially biologics, in the coming decade?

Biologics is a significant shift. Not all organizations can manage it due to its longer gestation period and high investments, but forward-looking companies are gearing up for it. We have been educating our members and emphasizing the importance of biologics. We accept this new form of medicine, but we cannot handle everything at the same time.

Government support will be essential. Our interaction with the government has notably increased, especially during and post the COVID period. The government understands our limitations. You might be familiar with the PLI schemes, which the Government has initiated.

Everything we do is patient centric, for the people of our Nation, as well as Globally. As you might recall, our Prime Minister mandated that we supply vaccines and medicines to all countries, while ensuring our own citizens arenâ??t neglected. This required strategic planning. We communicated to the public about the importance of avoiding panic buying to ensure the timely availability of medicines. This was a challenging task, but working closely with distributors, organizations like the AIOCD the All-India Organization of Chemists and druggists and various regulators, we were able to solve these issues collectively and successfully. The support we need is gradually coming through, not just for smaller entities but will eventually extend to all.

65 percent of Indiaâ??s APIâ??s needs are met by China. How do you explain this situation and how is it perceived by your members?

About 30 years ago, we were reasonably self-reliant in our basic requirements. However, China began dominating this market by significantly reducing prices. The Chinese government supported their manufacturers with incentives like free land, electricity, and cheap labour, enabling the swift establishment of manufacturing units. In contrast, in India, the process of setting up factories involves extensive time, potentially up to a decade or even a lifetime due to various regulations and relocation challenges. We have our distinct set of problems, goals, and priorities. The realization has dawned upon the government that we are highly dependent on another country with approximately 65 percent of our API needs, despite being one of the largest formulation suppliers.

Recognizing this, the government is initiating schemes to collaborate with us. However, the profit margins are not significantly attractive, dissuading many from entering this sector. Nonetheless, some individuals have a deep-rooted interest in manufacturing as itâ??s been their livelihood or family business. Thereâ??s a historical expertise in this area that, with government support, can be revitalized.

Our aim is to significantly reduce our dependence on external sources by at least 25-30 percent. We have certain members entering this field while supporting those already engaged in manufacturing to scale up their capacities.

Is there an element of overconfidence in India as to the industryâ??s future growth prospects?

Itâ??s not necessarily overconfidence, but the industry is seeing some positive results. While weâ??re not concerned with electronics or textiles, our focus is on our own industry. When our industry starts reaping the same benefits that others are, weâ??ll certainly see better performance. The government is instilling this confidence because medicines are an essential product. However, the market is still governed by various regulations and costs. Competition is so vast that nonsensical pricing of products is challenging. But where there is a lack of competition, the government intervenes. Some products are under price control, and those out of price control are also closely monitored. Even for those, unilateral price increases canâ??t happen without government approval, as it directly impacts peopleâ??s health and well-being.

What are the aims of the IDMAâ??s upcoming exhibition in January 2024?

The primary goal is to showcase the current state of the Indian pharma industry, highlighting our self-sufficiency. Itâ??s a platform for B2B meetings, attracting buyers and sellers from various segments such as packaging, laboratory equipment, API manufacturers, KSM manufacturers, and formulators, among others. Weâ??ve invited associations from different countries like, South Africa, Malaysia, LatAm, Argentina, Brazil, Indonesia, and more. Itâ??s about global connectivity and strengthening these connections in an industry thatâ??s rapidly expanding.

Concerns around the pharma industryâ??s future growth potential have been growing due to new pricing regulations in the US and Europe. What is your take?

Things are shifting, but it will ultimately be beneficial for patients. The Indian pharma industry is very patient-centric, and all changes ultimately strive to reduce prices, making medicines more affordable and accessible. In the US and the West, certain medications seem exclusive to the privileged, and thatâ??s something we oppose. Our goal is to provide medicines that cover a broader spectrum of people, making them accessible and affordable. Thereâ??s a need for a shift towards competitive prices that accommodate more people, especially considering that a significant portion of the population isnâ??t covered under insurance. Investing in medicines from India can extend healthcare access to a larger population.

Is there anything else that you would like to emphasize or add?

IDMA stands firm in supporting its members to meet global standards and prioritizes quality. Recently, weâ??ve been revising the Good Manufacturing Practices (GMP), and IDMA was the sole association mandated by the CDSCO and DCGI to conduct nationwide meetings to sensitize manufacturers. We hosted about 10 to 12 large gatherings without charging our members, conducting hybrid meetings with physical and online attendance. The meetings involved interactions with regulatory officials to address queries. This demonstrates our commitment to quality.

We introduced the National GMP Day, which was celebrated on October 10th, which will become an annual observance. While weâ??ve been devoted to maintaining quality, the objective is to ensure everyone comprehends and renews their pledge to excel further. We cannot compromise on medicine quality. India is acknowledged for its quality, volume production, and the reputation of being the pharmacy of the world.

Our government and Prime Minister advocate supporting the global population. We firmly believe that every individual has a right to access quality medicines for a healthy and longer life. India is an essential global player, and eventually, reliance on our medications or collaboration will be inevitable. While we do innovation, itâ??s crucial that our efforts are balanced and phased out, addressing the needs of our people, developing nations, and developed countries.

Every third tablet consumed in the world is made in India.

Every third child vaccinated is from a vaccine made in India.

Apart from our other goals and other objectives we want to ensure that every third pharmaceutical manufacturer in India is a member of IDMA.

The day is not far off for people across the globe to say: if it is medicine, it is INDIA.

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