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â??India is well-positioned to reduce its dependence on imported APIs and potentially challenge China's dominance in the global marketâ?•

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Formed in 1991 to encourage and formulate methods for developing bulk drugs indigenously for the local as well as export market, as an all-India representative body of the bulk drug industry, the Bulk Drug Manufacturers Association (India) (BDMA(I)) currently has over 350 member companies of which about 75 per cent are Micro, Small, and Medium Enterprises (MSMEs). The members of the association including the global ones such as Dr. Reddyâ??s Laboratories, Aurobindo, Lupin, Cipla, MSN, Hetero and Laurus are supplying Active Pharmaceutical Ingredients (APIs)to about 200 countries and have been dealing with regulatory agencies in different regions /countries. The association works as an interface between the Industry & Governments both at the Central and State levels and represents all common issues affecting the API industry with the sole objective of achieving growth in this sector. In an interview with BioSpectrum, R K Agarwal, National President, BDMA spoke about the challenges before the API sector and what is expected from the government to make India self-sufficient in this sector.



What are the primary challenges before the API sector in India, particularly concerning supply chain disruptions and dependency on imports?

The API sector in India is experiencing steady growth despite facing several significant challenges. One of the key issues is the storage and transportation of thermolabile drugs and cold chain-dependent pharmaceuticals, which still need improvement despite improvements in supply chain systems over the years. Additionally, compliance with newly introduced barcoding systems for API packaging presents another layer of complexity for the industry.

The Indian pharmaceutical sector continues to rely on certain imported APIs and drug intermediates, primarily due to cost considerations. While the Production Linked Incentive (PLI) schemes have been introduced to help address these issues, their impact has been limited, and the sector is still facing challenges in reducing dependency on imports.

How effective have the government's measures been in promoting domestic production?

The Indian government has implemented several strategic initiatives to strengthen the domestic production of APIs and reduce reliance on imports. One of the most notable efforts includes establishment of three Bulk Drug Parks across different states, supported by central assistance. These parks are designed to provide the necessary infrastructure and resources to facilitate large-scale API manufacturing, thereby boosting local production capabilities.

Another significant policy is the PLI scheme, which offers financial incentives for the domestic production of over 45 critical APIs and intermediates. This scheme has been widely praised for its potential to enhance the competitiveness of the Indian API sector and encourage investment in domestic manufacturing.

In addition to these initiatives, the government has provided indirect financial support for research and development by setting up Centers of Excellence at institutions like the National Institute of Pharmaceutical Education and Research (NIPERs). National labs, such as the Indian Institute of Chemical Technology (IICT) in Hyderabad and the National Chemical Laboratory (NCL) in Pune, are also playing a voluntary role in supporting R&D efforts, contributing to innovation and technological advancement in the sector.

The Department of Pharmaceuticals (DoP) is actively supporting the API and Micro, Small, and Medium Enterprises (MSME) sectors through various schemes aimed at strengthening the Indian pharmaceutical industry. These schemes focus on upgrading the quality infrastructure in individual units and pharmaceutical clusters, ensuring that the industry remains globally competitive.

Despite various government initiatives, India still relies on China for over 80 per cent of its API needs. How can this dependence be reduced?

India's reliance on China for over 80 per cent of its APIs stems from several critical factors, primarily related to cost and scale. The Chinese pharmaceutical industry has long been able to produce APIs at a lower cost due to economies of scale, substantial government support, and a well-established manufacturing infrastructure. These advantages have made Chinese APIs more affordable and attractive to Indian pharmaceutical companies, especially those focused on producing cost-sensitive generic drugs.

Recognising the strategic vulnerability of this dependency, both the Indian API sector and the formulations industry have acknowledged the urgent need for self-reliance in critical raw materials. This is particularly crucial to ensure supply chain stability during emergencies, such as global disruptions or geopolitical tensions.

The Government of India is acutely aware of this dependency and has introduced several initiatives to encourage domestic production. One of the key measures is the PLI scheme, designed to boost local manufacturing of APIs and intermediates. This scheme not only aims to reduce dependence on imports but also to counter potential price-cutting strategies that Chinese manufacturers might employ, as was seen in the past with the production of Penicillin and 6-APA ((+)-6-aminopenicillanic acid) in India.

As a result of these efforts, India's reliance on imported APIs and intermediates is gradually decreasing. However, a significant challenge remains. For instance, the Indian formulation industry, which is heavily oriented towards cost-efficient production, requires API manufacturing costs in India to be comparable to or lower than those in China. Until this cost parity is achieved, reducing imports will be difficult.

To further mitigate this dependency, India must continue to invest in scaling up its domestic API production capabilities, enhance R&D for cost-effective production processes, and provide sustained financial and infrastructural support to the industry. Only through these combined efforts India can significantly reduce its reliance on imported APIs and strengthen its position as a global pharmaceutical leader.

What kind of support, both financial and infrastructural, have you asked from the government to improve the API sector? How is the support from state and central governments enhancing the bulk drug sector in India?

As the National President of the BDMA, I have consistently advocated for comprehensive support from both the state and central governments to strengthen India's API sector. The primary areas where we've requested government intervention include financial incentives, infrastructure development, and regulatory facilitation.

Financially, we have urged the government to expand and enhance the PLI schemes, which are currently pivotal in promoting domestic API production. While the existing PLI schemes cover a range of critical APIs and intermediates, we believe there is room for broadening the scope to include more essential raw materials and intermediates. Additionally, we have asked for increased financial support for research and development (R&D) initiatives, particularly in developing non-infringing and cost-effective manufacturing processes. Enhanced R&D funding will help Indian manufacturers innovate and stay competitive on the global stage.

On the infrastructural front, the establishment of Bulk Drug Parks with world-class facilities is a major step forward. These parks are essential in providing the necessary infrastructure, such as common effluent treatment plants, utilities, and logistics, which are critical for reducing the cost of API production and ensuring environmental compliance. The central government’s initiative to set up three such parks with financial assistance is highly commendable, and we are working closely with state governments to ensure their timely and effective implementation.

Moreover, we've emphasised the need for streamlined regulatory processes to facilitate faster approvals and clearances, both for setting up new manufacturing units and for the export of APIs. Simplifying these processes will significantly reduce the time and cost involved in expanding production capacities, thus making the sector more agile and responsive to market demands.

Environmental regulations and policies often impact the API sector. How is the sector adapting to these regulations, and what are the major environmental challenges still haunting the sector?

The API sector in India has historically faced significant challenges related to environmental compliance, particularly concerning effluent treatment and waste management. Stringent environmental regulations have been implemented to ensure that the industry minimises its ecological footprint. However, these regulations have also posed substantial hurdles for manufacturers, requiring them to adopt advanced technologies and practices to meet compliance standards.

One of the major challenges has been the management of effluents, which, if not treated properly, can lead to severe environmental damage. The public perception of the API industry has often been negative due to concerns about pollution. However, the reality is that a majority of API manufacturers have made considerable strides in adopting best practices for effluent treatment. Many units have implemented state-of-the-art Effluent Treatment Plants (ETPs) that enable them to achieve zero liquid discharge, thereby significantly reducing the environmental impact.

To further support the industry in meeting these environmental regulations, the BDMA has been actively collaborating with the government. The association promotes government schemes that offer financial and technical assistance to API manufacturers for upgrading their environmental compliance infrastructure.

Despite these advancements, challenges remain, particularly in maintaining the delicate balance between stringent environmental regulations and the economic viability of API manufacturing. Continued efforts in innovation, coupled with robust support from government initiatives, are essential for the sector to overcome these challenges and sustain its growth while adhering to environmental norms.

Can India potentially lead the world in breaking China's dominance in the API market?

The Indian API industry is on a promising path towards achieving self-sufficiency and expanding its global footprint. While current capacities are growing, they are still evolving to fully meet both domestic and international demand. The PLI scheme and its forthcoming enhancements are pivotal in driving this transformation. By incentivising domestic production and reducing dependency on imports, these initiatives are expected to significantly bolster the sector’s capabilities.

What opportunities lie ahead for the API sector in India, and what strategies should be adopted to capitalise on them?

The API sector in India is poised for substantial growth, driven by opportunities in cost-effective manufacturing and innovation. To capitalise on these opportunities, the sector should focus on developing non-infringing processes through low-cost research. Achieving self-sufficiency in critical raw materials and intermediates will be crucial. Strategic investments in technology and process optimisation will further enhance competitiveness and resilience.

How do you see the API sector evolving in India over the next decade?

Over the next decade, the Indian API sector is expected to solidify its position as a global leader. With ongoing advancements in technology and increased self-reliance, India is well-positioned to reduce its dependence on imported APIs and potentially challenge China's dominance in the global market. The sector's growth will contribute to India's reputation as a leading global pharmaceutical hub.

Can you provide insights into the role of technology and innovation in enhancing the efficiency and competitiveness of the API sector in India?

Technology and innovation play a pivotal role in boosting the efficiency and competitiveness of India’s API sector. The government’s initiatives, such as collaborations with NIPERs and CSIR labs, are instrumental in driving technological progress. Programmes like Pharma Vision 2020 and the PLI scheme are specifically designed to stimulate innovation and optimise production processes.

Hyderabad’s NIPER, recognised as a centre of excellence in bulk drug manufacturing, exemplifies the impact of targeted support on industry advancement. This institute, along with similar organisations, is crucial in developing cutting-edge technologies and fostering research that enhances production efficiency.

These initiatives not only aim to improve domestic manufacturing capabilities but also position India as a competitive player in the global pharmaceutical market. By investing in technology and innovation, the Indian API sector is better equipped to meet international standards, reduce production costs, and advance its global standing.

Amguth Raju

hyderabad@mmactiv.com