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revise guidelines for of overcharging cases

bers and requested to send their comments if any, within 10 working days.

"The guidelines will stand deemed to be adopted if no comments are received," said the Authority.

It may be noted that the Ministry of Chemicals and Fertilisers has notified the amendment of the DPCO, 2013 in the end of June, with several changes including those related to overcharging cases.

The Ministry has amended Paragraph 14(2), which stipulated that the manufacturers selling a scheduled formulation at a higher price than the ceiling price and local taxes will be liable to deposit the overcharged amount with interest from the date of such overcharging, to include a proviso that the liability of the manufacturer for overcharging shall be restricted to the quantity of stock traded through the distributor or retailer, found to have effected such overcharging, if the manufacturer has been complying with the price revisions in the past.

This came as a relief to the manufacturers, since prior to the amendment, they would have been held responsible for overcharging and brought into the recovery proceedings even if they have complied with the regulations and the overcharging happened at the distributors', stockists' or retailers' end. ◆

Growing Indian API industry role in global supply chain

Dr. Sanjay Agrawal

India has established itself as one of the world's leading pharmaceutical manufacturing and exporting countries. While Indian pharmaceutical exports are widely recognised for generic medicines, Active Pharmaceutical Ingredients (APIs) are an equally important part of the country's pharmaceutical ecosystem. APIs are the biologically active substances in medicines that produce the intended therapeutic effect. Their quality, availability and cost directly influence the production, affordability and reliability of pharmaceutical products.

Over the years, India has developed significant expertise in API manufacturing, supported by a strong chemical industry, skilled scientific workforce, cost-effective production capabilities and a large network of pharmaceutical companies. Today, Indian API manufacturers supply pharmaceutical companies across major global markets, making the country an important component of the international pharmaceutical supply chain.

India's position in global API market

India has a diverse API manufacturing base, producing ingredients used in antibiotics, cardiovascular medicines, antidiabetic drugs, analgesics, antiinfectives, vitamins and several other therapeutic categories. The country has particularly strong capabilities in the production of generic APIs and pharmaceutical intermediates.

India's API exports have grown alongside the expansion of its generic pharmaceutical industry. The country's ability to manufacture APIs at competitive costs has made

Indian suppliers attractive to pharmaceutical companies looking to maintain affordable production while meeting international quality standards. The global API market is highly competitive, with countries such as China, India, Italy, Germany and several other manufacturing centres playing significant roles. India has developed a strong position because of its ability to combine relatively low manufacturing costs with technical expertise and experience in supplying regulated international markets.

Major drivers of API exports

One of the most important factors supporting India's API exports is cost competitiveness. Indian manufacturers benefit from an established pharmaceutical and chemical manufacturing ecosystem, a large skilled workforce and extensive experience in process optimisation and large-scale production. India also has a strong base of scientific and technical professionals, including chemists, pharmacists, engineers and researchers. Their expertise supports manufacturing, quality control, process development and regulatory compliance.

Another important advantage is vertical integration. Several Indian pharmaceutical companies operate across multiple stages of the pharmaceutical value chain, from raw materials and APIs to finished formulations. This integration can provide greater control over quality, costs and supply reliability. India's experience with international regulatory systems is another significant strength. Manufacturers supplying markets such as the United States and Europe have developed capabilities in Good Manufacturing Practices, documentation, quality management, inspections and regulatory submissions.

Government support for API manufacturing

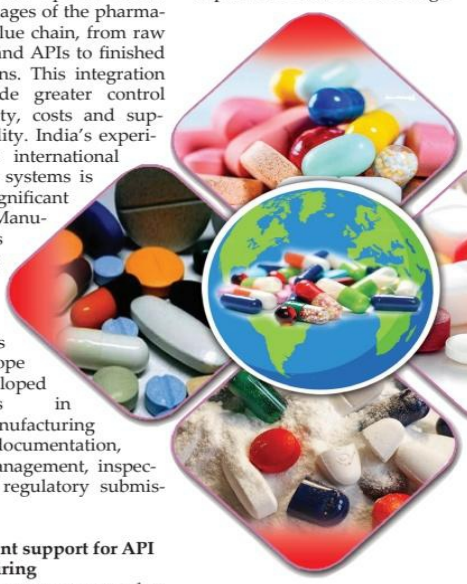
The Indian government has increasingly recognised the strategic importance of domestic API manufacturing. Historically, India has depended substantially on imports for certain APIs, key starting materials and pharmaceutical intermediates. This dependence has highlighted the need to strengthen domestic manufacturing capacity.

Several government initiatives have therefore been introduced to encourage investment in the bulk-drug and API sector. The Production Linked Incentive scheme for bulk drugs focuses on increasing domestic manufacturing of critical APIs, Key Starting Materials and drug intermediates.

Such initiatives are important for two reasons. First, they can reduce India's dependence on imported pharmaceutical inputs. Second, they can create additional manufacturing capacity that can eventually support exports. The development of domestic API capacity also improves India's resilience against global supply-chain disruptions. Events such as the Covid-19 pandemic demonstrated how disruptions in international logistics and manufacturing can affect the availability of critical pharmaceutical ingredients.

Major export markets

Indian pharmaceutical manufacturers supply APIs and pharmaceutical products to a wide range of international markets. The United States and European countries remain particularly important because of their large



pharmaceutical industries and stringent but established regulatory frameworks. The United States is one of India's most significant pharmaceutical trading partners. Indian manufacturers have extensive experience supplying products to the US market, although competition and regulatory requirements remain demanding.

Europe is another major opportunity for Indian API manufacturers. European pharmaceutical companies increasingly value reliable and diversified supply chains. Indian manufacturers that can consistently meet European quality and environmental standards are well positioned to benefit from this demand. Beyond developed markets, Africa, Latin America, Southeast Asia and other emerging regions offer considerable opportunities. These markets have growing healthcare needs and significant demand for affordable medicines. As local pharmaceutical manufacturing expands in these regions, demand for APIs and pharmaceutical intermediates is also expected to increase.

Challenges for Indian API exporters

Despite India's strengths, the API export industry faces several challenges. The most significant is intense international competition, particularly from China. Chinese manufacturers have considerable scale and strong positions in numerous APIs and intermediates. Indian companies therefore need to compete on more than price by offering consistent quality, supply reliability and technological capabilities.

Regulatory compliance is another major challenge. Pharmaceutical markets increasingly demand strict standards relating to manufacturing processes, quality control, data integrity and environmental practices. Meeting these requirements requires continuous investment in facilities, technology, skilled personnel and quality systems.

Raw-material dependence can also affect India's competitiveness. Even though India has a strong API industry, certain starting materials and intermediates continue to be sourced internationally. Price fluctuations, geopolitical developments and transportation disruptions can therefore influence production costs.

Environmental sustainability is becoming another important consideration. API manufacturing can involve substantial use of water, solvents, chemicals and energy. International customers and regulators are increasingly focused on environmentally responsible production. Indian manufacturers will need to adopt cleaner technologies, improve waste management and reduce their environmental footprint.

Opportunities for future growth

The future of Indian API exports lies not only in increasing production volumes but also in moving towards higher-value and technologically advanced APIs. Complex APIs, speciality pharmaceutical ingredients, high-potency products, peptides and other sophisticated products could offer significant growth opportunities.

Investment in research and development will be crucial. Companies that improve manufacturing processes, develop innovative synthesis methods and reduce production costs can gain a stronger competitive advantage in international markets.

Greater backward integration can also strengthen India's position. Developing domestic sources for important raw materials, starting materials and intermediates would reduce supply-chain risks and improve India's ability to provide reliable long-term supplies to global customers. Market diversification will be equally important. Expanding exports to emerging markets can reduce dependence on a small number of countries while creating new opportunities for Indian manufacturers.

Conclusion

Exports of Indian API products have become an important component of India's pharmaceutical industry and its position in the global healthcare ecosystem. India's combination of manufacturing expertise, scientific talent, cost competitiveness and experience with international markets gives it a strong foundation for continued growth. Government support for domestic API manufacturing is also strengthening the country's pharmaceutical supply chain and reducing dependence on imports of critical ingredients. However, Indian manufacturers must continue to address challenges related to international competition, regulatory compliance, raw-material security, technology and environmental sustainability.

The next phase of growth will depend on India's ability to move beyond conventional, cost-driven API manufacturing and develop high-quality, complex and technology-intensive pharmaceutical ingredients. With continued investment in innovation, infrastructure, research and regulatory excellence, India can strengthen its position as a reliable global supplier of APIs. Ultimately, growth in Indian API exports will not only boost pharmaceutical exports and economic development but also reinforce India's role as a key supplier in the global healthcare system. ◆

(The author is pharma consultant)