Port offices on September 12. The guidelines were last released in 2011, and the recent changes—including the introduction of new rules and regulations and the online system through the SUGAM portal—necessitated the revised order in line with the procedures followed in CDSCO offices.

Speaking on the new CDSCO guidelines, the IRGMA General Secretary Man Mohan Singh Gulati said, "The new guidelines issued by CDSCO are a welcome step. However, the implementing authorities, including ADCs posted at ports, must be made aware of the document to effectively control the import of substandard bulk-packed gloves."

The association has long been demanding the Quality Control Order (QCO) for gloves to keep substandard imports at bay and urged the government to expedite its process. This will not only help Indian manufacturers but also contribute to the union government's Make in India initiative to achieve self-sufficiency and reduce dependence on other countries.

The IRGMA general secretary added that the new CDSCO guidance document will bring uniformity, transparency, predictability, and accountability to all offices, incorporating risk-based inspections as part of the organization's technical functions.

Weakness in API Prices to Persist: India Ratings

Mumbai, India: India Ratings and Research expects active pharmaceutical ingredient API prices and volume growth to remain weak for India in FY25, driven by imports and competition in exports, both from China. However, low raw material prices have mitigated the impact of the price decline. This along with costs and forward integration into the formulations business (which has seen higher prices in the regulated markets) has caused EBITDA margins to expand.

This had led to a higher count of positive directional actions on its pharma portfolio over the past 12 months. A wider basket of products across therapies and lower concentration of products exposed to Chinese competition have also led to a healthy financial performance for India Ratings rated pharma companies.

API price decline has ranged from 20% - 50% in key molecules over the past 12 months. While steep price declines have abated since 2QFY25, given prices reaching uneconomical levels even for Chinese players (import prices have declined over 50% yoy in some cases), Ind-Ra opines pricing challenges will persist, primarily led by competition from Chinese players in key large volume molecules.

The agency has also observed significant increase in imports of drug intermediates/bulk drugs used for manufacturing API/formulations from China which have accentuated the downward momentum in realisation. While exports of APIs to regulated markets are long term in nature where the pricing erosion may not be severe, the agency believes Chinese competition may lead to a steep erosion in pricing and profitability in markets excluding regulated ones.

Revenues of Indian pharma companies likely to expand by 9-11% in FY2025: ICRA

Mumbai, India: ICRA expects the revenues of its sample set of companies to expand by a healthy 9-11% in FY2025, albeit a moderation from the YoY increase of 13-14% recorded in FY2024. This will be driven by 9-11% revenue growth from the US market, 7-9% each from the European and domestic markets, and 11-13% from the emerging markets. ICRA's Stable outlook on the industry reflects the steady growth expectations across key markets and the healthy credit profile of pharma players.

Commenting on the near-term expectations of the industry's operating profit margin (OPM), Kinjal Shah, Senior Vice President & Co-Group Head – Corporate Ratings, ICRA, said: "ICRA expects the operating margins of its sample set of companies to remain stable at 23-24% in FY2025, supported by an increase in revenues, higher contribution of complex generics/ specialty molecules and soft prices of raw materials."

ICRA expects the revenue growth from the domestic market for its sample set of companies to improve to 7-9% in FY2025 against 6.4% in FY2024. Growth in the previous fiscal was impacted to an extent by the change in the composition of the National List of Essential Medicines (NLEM), which resulted in a decline in realisations for certain drugs, in addition to an uneven monsoon, which affected acute therapy sales.

In contrast, in Q1 FY2025, ICRA's sample set of companies witnessed a YoY increase of 11.7% in revenues as some of the players gained market share in chronic therapies and enjoyed continued benefits from the introduction of new products.