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Maharashtra FDA Cancels Drug Sale Licence of Cipla's Pune C&F Unit Over Compliance Irregularities

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Regulatory action follows inspections that flagged stock discrepancies, storage deficiencies and alleged non-compliance with a recall order; Cipla contests the decision and says the order raises no concerns over product safety, quality or efficacy



In a significant regulatory development for India's pharmaceutical distribution ecosystem, the Maharashtra Food and Drug Administration (FDA) has cancelled the drug sale licence of a Pune-based Carrying and Forwarding (C&F) unit of Cipla Pharma & Life Sciences Limited following the identification of multiple compliance irregularities.

The action, which came into effect on Thursday, follows regulatory scrutiny of the unit's drug storage and distribution practices, including issues related to stock management, storage infrastructure, handling of expired medicines and compliance with an earlier recall direction.

The development brings renewed attention to the increasingly rigorous compliance expectations surrounding pharmaceutical distribution and supply-chain operations in India, where maintaining product integrity extends well beyond manufacturing facilities to warehousing, inventory management, documentation, recalls and downstream distribution.

Reactin Plus inspection triggers regulatory scrutiny

According to the Maharashtra FDA, an inspection conducted in June identified concerns relating to Reactin Plus Tablets, a prescription medicine.

Officials reportedly found that the medicine's packaging carried an unauthorised claim describing the product as an "analgesic and antipyretic".

Following the inspection, the regulator seized stock valued at approximately Rs 11.19 lakh and directed the company to recall the tablets it classified as "misbranded". The FDA subsequently alleged that the recall directions were not fully complied with.

The regulator's concerns, however, extended beyond the product labelling issue.

A further inspection of the C&F unit's drug sale and distribution system identified what the FDA described as improper storage arrangements and discrepancies between purchase and sale records and computerised inventory.

The inspection also reportedly found differences between physical stock and computerised records, inadequate pallet and rack arrangements, and deficiencies in the documentation and procedures used for handling expired medicines.

Medicines were also reportedly found stored directly on the floor at the facility.

Together, these findings prompted the state regulator to move beyond corrective observations and take the more consequential step of cancelling the unit's drug sale licence.

Drug distribution emerges as a critical compliance frontier

The regulatory action highlights an important dimension of pharmaceutical quality management: compliance does not end when a medicine leaves the manufacturing line.

For pharmaceutical companies operating increasingly complex distribution networks, C&F facilities form an important bridge between manufacturers and downstream markets. Inventory reconciliation, appropriate storage, traceability, recall execution and documentation therefore remain integral elements of pharmaceutical quality and supply-chain governance.

The Pune development illustrates how regulators are scrutinising not merely the quality of medicines themselves, but also the systems responsible for storing, tracking, recalling and distributing them.

In an industry where supply chains have become more sophisticated and increasingly digital, discrepancies between physical inventory and electronic records can attract significant regulatory attention. Equally, an effective recall mechanism depends on companies being able to rapidly identify affected inventory, trace its movement and demonstrate that regulatory directions have been implemented.

Maharashtra FDA signals stricter enforcement

Maharashtra FDA Commissioner Tukaram Mundhe indicated that the regulator intends to maintain a firm approach towards violations across the pharmaceutical manufacturing and distribution chain.

“Any violation of rules by any entity involved in the manufacture and distribution of medicines will invite strict action as per law,” Mundhe said, adding that the department would not show leniency on matters concerning drug safety and public health.

The statement signals the regulator’s broader emphasis on accountability throughout the pharmaceutical value chain, particularly as India continues to strengthen its reputation as one of the world’s most important pharmaceutical manufacturing and supply hubs.

The episode could consequently have relevance beyond an individual C&F facility. Robust warehousing practices, real-time inventory reconciliation, documented procedures for expired medicines and demonstrably effective product-recall systems are becoming increasingly important components of pharmaceutical compliance.

Cipla contests FDA order, says no product safety concerns alleged

Cipla Pharma & Life Sciences has contested the Maharashtra FDA’s decision.

The company has also sought to distinguish the regulatory proceedings concerning the C&F operation from the safety and quality profile of its medicines.

“As the issue is under judicial consideration, it would not be appropriate to comment further on the proceedings at this stage,” the company said.

Importantly, Cipla further clarified that the order does not allege concerns relating to the “safety, quality or efficacy” of its products and, according to the company, does not involve or indicate a patient-safety issue.

The matter is therefore now characterised by two distinct positions: the Maharashtra FDA’s enforcement action based on alleged regulatory and distribution-system irregularities, and Cipla’s decision to contest the order while emphasising that the action does not allege deficiencies in product safety, quality or efficacy.

Why the development matters for India’s pharma industry

For India’s pharmaceutical sector, the Pune case underscores the widening definition of quality and compliance.

Historically, conversations around pharmaceutical quality have often centred on manufacturing plants, Good Manufacturing Practices (GMP), laboratory controls and finished-product testing. But modern pharmaceutical oversight increasingly encompasses the entire product journey — from manufacturing and release to storage, transportation, inventory control, distribution and, when required, recall.

This makes C&F operators, warehouses and distribution centres increasingly important components of a pharmaceutical company’s overall quality architecture.

As Indian pharmaceutical companies expand both domestic and international operations, stronger integration between quality systems and supply-chain infrastructure will be essential. Accurate digital and physical inventory reconciliation,

documented storage practices and rapid recall execution are not simply operational efficiencies; they are increasingly fundamental regulatory requirements.

The Maharashtra FDA action serves as a reminder that regulatory compliance must remain continuous across the pharmaceutical value chain.

For companies, the larger takeaway is equally clear: **the integrity of a medicine is protected not only by how it is manufactured, but also by how effectively it is stored, documented, traced, distributed and, when necessary, recalled.**

Cipla Pharma & Life Sciences Limited is an entity associated with Cipla Limited. The regulatory matter concerning the Pune C&F unit remains under judicial consideration.

Editor's Note

This is a developing story. BioSpectrum India will continue to follow the developments closely and update this report as further information and official responses become available.