CASE STUDY

Fortrea Call Center strategy for handling product recall experience

A KEY QUESTION

How does Fortrea help sponsors manage high-volume, safety-critical product recalls through its Medical Information Contact Center (MICC), while maintaining regulatory compliance, operational efficiency and patient safety?

KEYWORDS Voluntary Product Recall, Call Center, Post-Marketing Safety

About the sponsor

The sponsor is a research-led, global company involved in developing and commercializing pharmaceutical products with a focus on several key therapy areas and operations in over 80 countries.

In its quest to be among the first few pharmaceutical companies to develop an innovative drug for the world, it is treading two parallel paths. One path pursues the discovery of a novel chemical or biological entity. The second leads toward scaling the value chain by creating specialty products that address gaps in treatment.

The sponsor has focused on building a global Innovative/Specialty, Generics and OTC business. It also has a strong regional/country-specific presence in other therapeutic areas like diabetes, cardiovascular and oral contraceptives.

Case study details

This case study illustrates a specific instance of drug recall (class II).

The Fortrea Medical Information Contact Center (MICC) provides a critical role in product recalls by acting as the central hub for communication between pharmaceutical companies, healthcare professionals, patients and regulatory authorities. During recall, MICC disseminates accurate information based on Labels (Patient Information Leaflet and Summary of Product Characteristics) and Frequently Asked Questions, manages high volumes of inquiries and provides standardized responses to deliver clarity and compliance.

Fortrea

As it was a voluntary recall initiated by the sponsor at the retail level, it involved the prescription product concerned.

The recall at the retail level was identified for multiple batches. This recall was initiated out of an abundance of caution due to the presence of an impurity above the current Acceptable Intake (AI) level in certain batches. These impurities may increase the risk of cancer if people are exposed to them above acceptable levels over long periods of time. There is no immediate risk to patients taking the medication.

The sponsor requested all the distributors/wholesalers and retailers to examine their inventory for the identified batches. They were instructed to quarantine these batches immediately and not dispense any further product from the identified batches/lots.

The sponsor requested the batches specified to be returned using the "Postage Paid Product Return label" that was provided in the Recall Return Packets.

This recall was made with the knowledge of the U.S. Food and Drug Administration.

In February 2025, the Fortrea MICC team was made aware of the voluntary recall, leading to an unplanned surge in calls/inquiries. Since then, the recall inquiries started coming in and approximately 5,000 inquiries were received and completed by Fortrea.

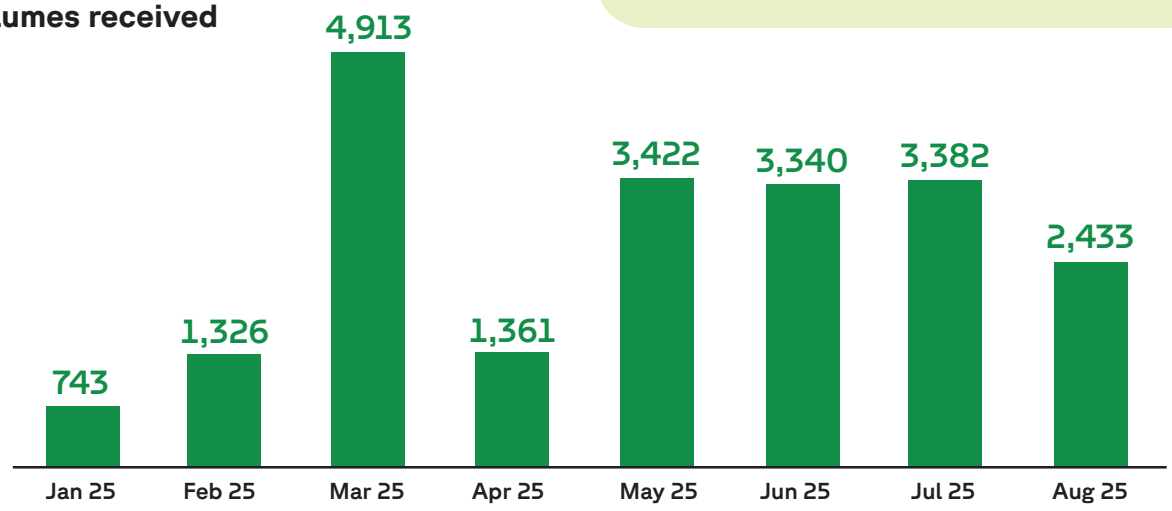
This recall led to a significant increase in volumes, as depicted in Figure 1 below.

Volume surge

Fortrea MICC capacity: 45 inquiries/day
Volume surge: 250+ inquiries/day
From: January 2025 to August 2025

Fig. 1

Volumes received



The recall was effectively executed through a coordinated approach that involved comprehensive cross-training of all Fortrea local affiliates to confirm alignment with recall procedures, regulatory compliance and operational readiness. In parallel, additional manpower was strategically allocated across to manage increased workload demands, facilitate timely communication with stakeholders and drive seamless execution across the affiliates. This proactive resource optimization enabled Fortrea to manage the recall process with efficiency, accuracy and minimal disruption to ongoing operations.

Recall management at Fortrea

In February of 2025, the team was alerted to the product recall by the sponsor. Within the first hour, an unusual increase in inquiries was observed, prompting immediate notification to the sponsor's core team and Sponsor Point of Contact.

A Task Force involving various departments was established to address the influx of inquiries related to the recall:

- Project management
- Operations oversight
- Data quality reviews
- Mailbox management

The supplementary workforce from the Fortrea India team was contacted and engaged to assist the U.S. team. The team carefully and thoroughly transcribed and assessed the initial information. The sponsor agreed to Fortrea's suggestion to involve other affiliate members to expedite the inquiries. The team was encouraged to increase their working hours and make efforts to safeguard efficient management of the inquiries queue and backlog.

Mastering the recall: Steps toward excellence

Only specific team members are designated to work for a specific affiliate and in this scenario, all the other affiliate members were utilized to control the upscaling workflow. To avoid this in the future, other affiliate team members were utilized to support completion of backlog inquiries. A deviation was filed for utilizing members from Fortrea of different affiliates and the KPIs/SLAs could not be met due to this surge. Also, a new Interactive Voice Response had to be developed to manage these recall volumes.

The Fortrea team performed adverse event reporting, supported pharmacovigilance teams and documented all interactions for regulatory audits. By coordinating closely with quality assurance, regulatory affairs and supply chain teams, the MICC helped deliver timely, transparent and effective recall execution, safeguarding patient safety and maintaining regulatory trust.

Steps involved in orchestrating end-to-end workflow activities involved:

- Cross training was provided for the team members to help complete the surged volumes
- The inquiries were assessed, and complexity of work was determined
- Teams prioritized tasks according to case type
- Daily progress was monitored to maintain team performance and prevent burnout
- Daily dashboard on the volumes v/s processed data was published internally and provided to the sponsor

Global effort outcome/conclusion

In April of 2025, the backlog of all recall inquiries was cleared. While managing the recent product recall, the team observed an unexpected surge in case volume, which presented several operational and compliance challenges. These included resource constraints, increased documentation demands and the need to maintain quality and consistency under time-sensitive conditions.

Rather than postponing acknowledgment of these pressures until the conclusion phase, the team took a **proactive and transparent approach** by initiating a formal deviation early in the process. This action allowed us to:

- **Maintain regulatory compliance** through timely documentation of the nonconformance
- **Demonstrate due diligence** in identifying and managing operational risk
- **Enable real-time corrective measures** by facilitating cross-functional awareness/trainings and decision-making
- **Safeguard audit-readiness** with a clear trail of rationale and mitigation steps

Over a sustained period of approximately six months, Fortrea successfully managed a high volume of recall-related calls, confirming consistent, responsive and empathetic support to both consumers and pharmacists. The recall was handled with a strong focus on service excellence and operational efficiency.

Real-time communication was maintained with the sponsor, enabling continuous oversight and informed decision-making throughout the process. Concurrently, all voluntary product recalls were transparently reported to the Food and Drug Administration, reaffirming our commitment to regulatory compliance and patient safety.

By leveraging internal (Fortrea) team members to manage recall volume, companies may achieve significant cost reductions by:

- **Avoiding third-party service fees**
- **Maximizing existing workforce capacity**
- **Streamlining coordination and communication**

Significant time was saved by assigning recall management to internal team members who were already trained on the process, resulting in:

- **No additional training required, eliminating onboarding delays**
- **Immediate execution with full process familiarity**
- **Faster cross-functional coordination due to established workflows**
- **Accelerated issue resolution, minimizing disruption**

This approach enabled the team to respond swiftly and efficiently, saving critical hours and days across multiple recall phases—from initiation to closure.

This approach led to more efficient recall execution and lower operational costs, especially in high-volume scenarios where external support would have been costly and slower.

This initiative exemplifies Fortrea's role as a trusted strategic ally—collaborating seamlessly with the sponsor to navigate complex recall operations with precision, agility and deep pharmacovigilance proficiency.

From a regulatory perspective, this approach reflects Fortrea's commitment to robust quality systems and continuous improvement, as required and relevant standards. The deviation was documented in accordance with the Fortrea Corrective Action and Preventive Action and deviation procedures, including an impact assessment and justification for the temporary adjustments made.

For internal and external stakeholders, this deviation served as a structured communication tool that confirmed alignment between Quality, Operations and Regulatory teams. It allowed the sponsor to reallocate resources efficiently and implement temporary procedural flexibilities while preserving product integrity and patient safety.

By addressing the challenge at the onset, rather than in retrospective conclusions, the team had mitigated risk, upheld compliance and demonstrated a proactive quality culture.

The sponsor acknowledged Fortrea's effective management of the product recall with appreciation. The recall inquiries are in decline, and the team has resumed working as per daily routine.

Contact our team to learn more about how Fortrea's Post-Marketing Safety Services can help you with your product and patient safety needs.

LEARN MORE at fortrea.com

Fortrea