RESOURCES

Home

Fixing Recalls: FDA Pilot Tackles a Legacy Challenge—7 Broken Practices and 5 Guiding Principles for Change

The time has come to fix recalls.

Pharma supply chain companies work diligently to optimize internal product recall practices and ensure high levels of patient care. But the industry is constrained by an inability to share information freely across the supply chain. The result is a recall process that is complex and characterized by disconnected systems, error-prone manual procedures, less-than-perfect or missing data, and a lack of inventory visibility that makes it difficult to find affected products. Worse, it’s potentially dangerous for patients.

The good news is that incremental changes to the process based on a set of fundamental principles can lay the groundwork for establishing an end-to-end, cloud-based digital recalls network that would simplify process orchestration for all supply chain stakeholders and improve patient safety, according to the results of a recent US

Food and Drug Administration (FDA) pilot.

A cross-functional team of industry leaders from each segment of the US pharmaceutical supply chain, including TraceLink, collaborated under the FDA Pilot Project Program for six months in 2019. The team also included pharma companies, contract manufacturers, third-party logistics providers, wholesalers, and retail and healthcare system pharmacies.

The pilot team went through two steps. First, the team sought to identify inefficiencies in the recalls process. The result was a list of seven steps in the recalls process that need significant improvements. Second, the pilot team defined steps needed to develop a digital recalls network. The result was a list of five principles to guide an improved recalls process.

The trouble with recalls: 7 practices that need to be rebooted

The pilot team closely examined seven key steps associated with recalls across the supply chain. Here's a rundown of the key insights:

1. Initiation of a recall event

Standard operating procedures for initiating a recall tend to vary from pharma company to pharma company. Most often, the company's quality management team leads a recall committee with stakeholders from across the organization and facilitates the recall execution. The quality team also works with the FDA to get notifications classified

and approved.

Pharma companies often use a reverse logistics company to manage all or part of the recalls process. Communication between pharma companies and reverse logistics companies occurs primarily over email and phone and depends on information that resides in disparate systems across the two organizations. The recall manager on the pharma company's quality team generally spends a great deal of time identifying customers potentially affected by the recall and aggregating the list of ship-to location addresses that must be notified for each recall event.

2. Communication of the initial recall notice

Recall notifications and instructions are typically communicated via a mix of email, and fax, and packages sent via FedEx or other carriers. Some of the challenges pharma companies face when distributing recall notices include:

- Notifications are sent to a regional distribution center, but not to the current location of product within a healthcare system or pharmacy chain.
- Notifications are sent to the right company and location but are not received by the person responsible for coordinating recalls.
- Notifications are lost.
- Notifications are refused due to data entry or labeling errors.
- Notification recipients no longer have the recalled product in their possession.

Additionally, due to the manual nature of most recall communications and variability in how recipients process notifications, pharmaceutical companies are usually unable to gain a clear picture of the success of a recall notification.

3. Communication of a sub-recall or forward-recall notification

Wholesale distributors are responsible for sending sub-recall or forward-recall notifications to direct trade partners, including secondary distributors, retail pharmacies, and healthcare organizations. But the information distributors receive to support sub-recall execution can vary widely—and information found in recall notifications is currently not tied to tracking data associated with US Drug Supply Chain Security Act (DSCSA) compliance processes.

Additionally, recall coordinators at wholesale distributors may not have the ability to determine locations of affected lots within the distribution environment and sometimes lack the ability to determine to whom affected lots have been sold.

4. Receipt of a recall notice

Managing recalls at retail and healthcare pharmacies typically involves disjointed communications from upstream partners and time-consuming manual procedures. Some of the challenges dispensers face include:

- An average of 20 to 30 drug recall events that need to be managed at any given time.

- Multiple notifications for the same product.
- Recall notifications are frequently received for products that were never received by the dispensing organization.

As a result of these challenges, dispensing organizations often experience “alert fatigue” as notices stack up and the time to execute a recall grows.

5. Identification and removal of recalled product

Due to a lack of full visibility into the location of inventory, all pharmacy locations within a given health system or retail chain usually need to be physically searched to identify and remove recalled product.

Information such as pertinent lot numbers is often missing from inventory records, forcing many pharmacies to remove all lots under each NDC in the recall notice—even lots that are not being recalled. This leads to unnecessary waste and is a contributing factor to drug shortages.

6. Communication with patients

The pilot team found that there is a strong sense of urgency to ensure patients are not harmed by recalled products. But steps taken to notify patients can be complicated by many factors.

For example, dispensing records generally do not contain dispensed NDC or lot information, making it difficult to identify impacted patients. Pharmacies compensate

by informing as many patients as possible, but this broad outreach can lead to confusion among patients who are unsure if they really do have the recalled product in their possession.

7. Monitoring the effectiveness of recalls

In addition to pharma companies, multiple organizations orchestrate the recall execution process, including returns processors, contract manufacturers, and direct trade partners such as wholesale distributors, pharmacies, and hospitals.

Given the challenges that pharmaceutical companies have with respect to precise visibility of the quantity, location, and status of their medicines in the supply chain, procedures for monitoring the progress of a recall event and performing effectiveness checks are complex and imprecise.

The path forward: 5 principles to guide an improved recalls process

These manual, time-consuming, and error-prone methodologies for initiating, notifying, executing, and closing recall events underscore the pressing need to build a better approach—a digital recalls network. Key capabilities would include the ability to leverage new types of information and bring to bear advanced network approaches for connecting companies, sharing information, and orchestrating processes across the end-to-end supply chain.

The pilot program identified five key principles that will establish guidelines for the creation of such a digital recalls network and ultimately help reduce the time, cost, and risk of managing the recalls process. These include:

1. Transform today's manual, disconnected recalls notification and acknowledgement process into an electronic, bi-directional, recall communication workflow.

2. Increase the interconnectivity and interoperability between systems used for recalls initiation and management and systems used for product identity, product traceability, and product inventory management.

3. Develop a network shared data model for recalls that would leverage DSCSA-driven data—such as lot-level transaction information and the serialized product identifier—and integrate it with information captured and shared today via recall notices, business response cards, and other documents.

4. Share unit-level product status information across serialization, traceability, and inventory systems to inform operational processes—such as distribution, pharmacy, and inventory management—and alert personnel to potentially recalled products in an organization's possession.

5. Strengthen the linkage between organizations and systems that make up the end-to-end recalls process, across both forward and reverse logistics, to establish greater closed-loop visibility into the status of an executed recall.

Whether taken as a whole or implemented incrementally over time, these principles establish the foundation for an open, interoperable, standards-based digital recall network that would provide immediate benefit to all stakeholders and make the end-to-end recalls process faster, more precise, and ultimately, safer for patients.

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