

Enhancing Patient Safety Through a Global Standards-Based Product Recall Communication Service



Product Recalls Today: The Problem

Drug recalls have increased more than **65%** over the past ten years.*

*Calculated based on data from: <http://www.healthycanadians.gc.ca>

Challenges with Drug Recalls

- Delayed recall notices to pharmacies
- Lack of standardized recall information
- Lack of automated processes
- Extensive time creating recall notifications and reporting
- Lack of traceability

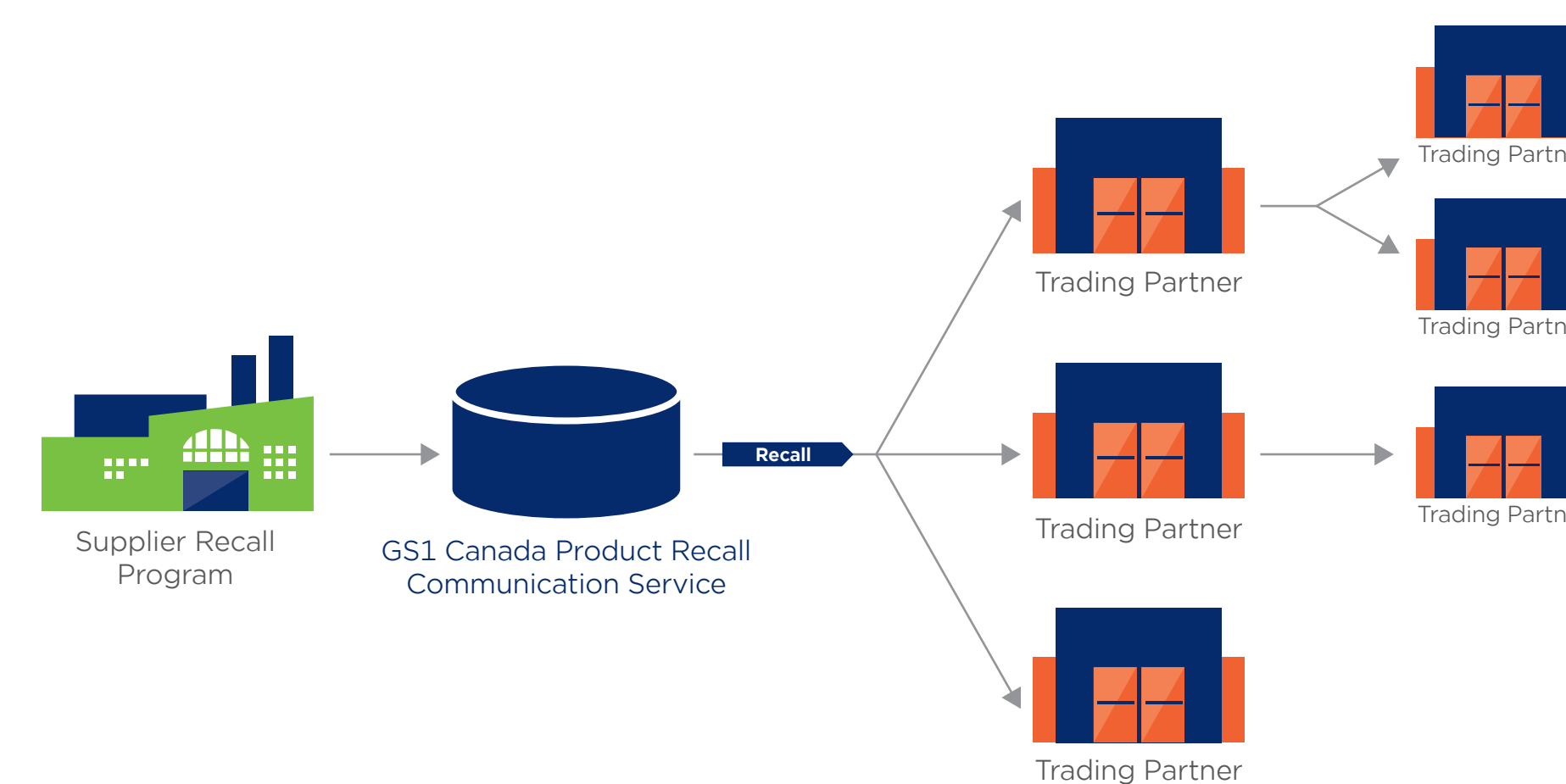
The Impact of a Flawed Process

When a drug is recalled, time is of the essence. Lives depend on the immediate removal of the drug being dispensed or accessed by patients.

Solution to the Problem

To improve the effectiveness of pharmaceutical product recalls in Canada, the pharmacy sector worked collaboratively with GS1 Canada to establish a global standards-based product recall communication and recall ready service, aligned with Health Canada recall policy. GS1 Canada's Product Recall is a web-based communication service that drives the speed, accuracy and traceability of product recall notifications, resulting in improved efficiency and patient safety. GS1 Global standards driving this service include Global Trade Item Number (GTIN), Global Location Number (GLN), and Global Document Tracking Number (GDTI).

Using GS1 Canada's Product Recall service, manufacturers can rapidly and efficiently share real-time product notifications with their trading partners in a secure and one-to-many process. This means manufacturers file once to expeditiously inform multiple trading partners, and obtain their acknowledgement of receipt of the notification through the system.



Product Recall Service Pilot Objective

The objectives of the 2014 Pharmaceutical Product Recall pilot were to ensure patient safety, improve system efficiencies and facilitate a more secure pharmaceutical supply chain, using GS1 Canada's Product Recall service.

Methodology

GS1 Canada conducted a pilot that simulated real-life recall scenarios, involving multiple segments of the supply chain. Methods included validating the product recall attributes, documenting future state workflows from the manufacturer to the distributor and each of the participating hospitals and pharmacies, and demonstrating the value proposition through quantitative and qualitative metrics.

Before completing the pilot, participants were trained and carried out a mock recall in order to be deemed "recall ready".

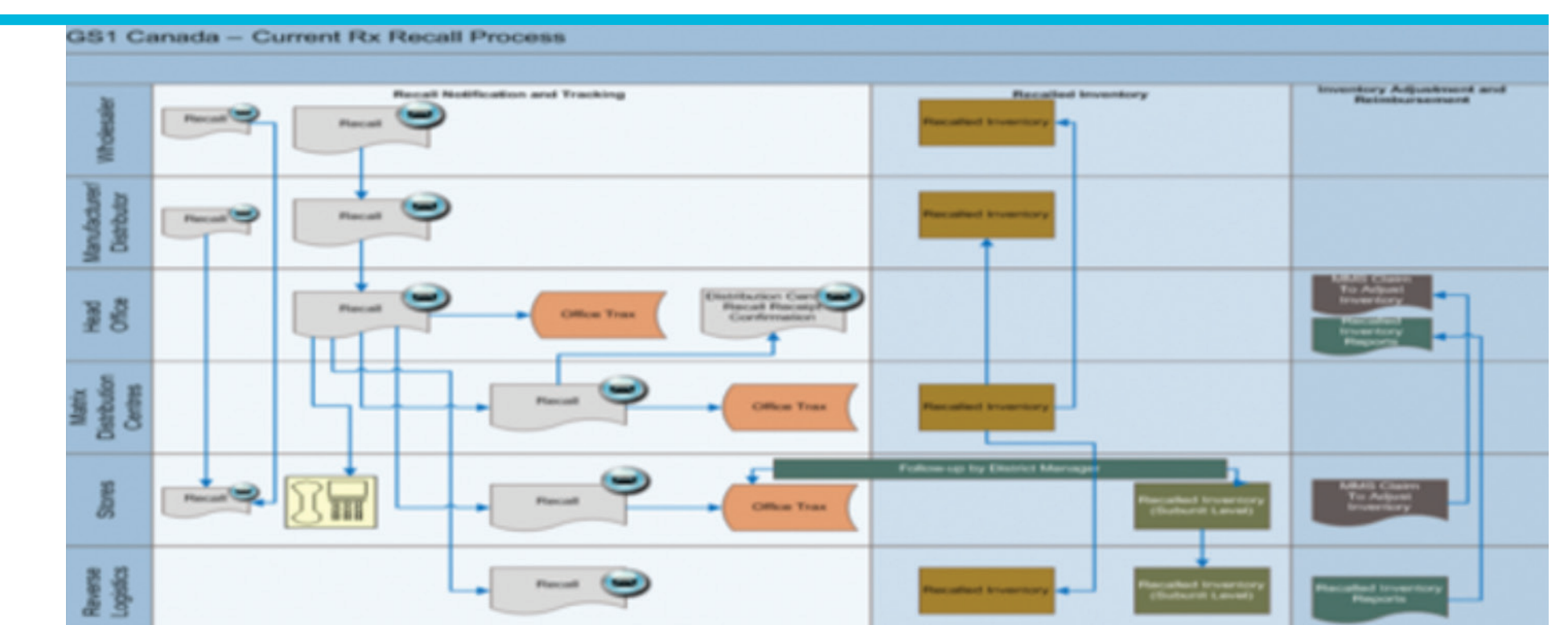
Participants included:

- Pharmaceutical manufacturers
- Provincial, multi-site hospital pharmacies and a central pharmacy procurement centre
- Distributors
- Multi-site chain and banner retail pharmacies with corporate head office

Pilot Findings

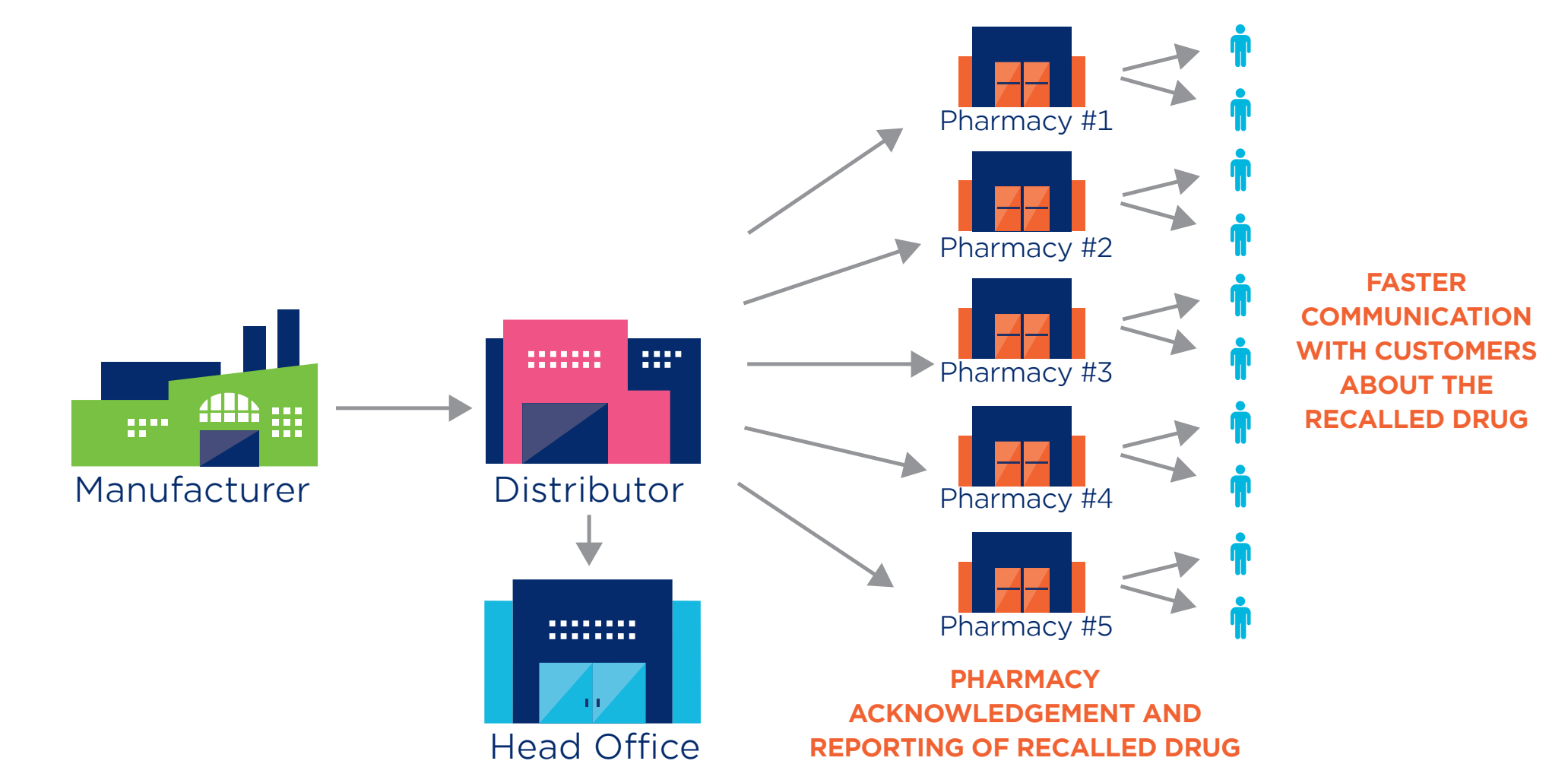
Before the pilot: Recall Process Workflow

- Inefficient
- Complex
- Manual
- Inconsistent reporting
- Inconsistent returns of the recalled drug



During the pilot: Recall Process Workflow

- Standardized
- Speed and ease of use
- One-to-many communications
- Automated process and reporting
- Traceability and reporting



The pilot demonstrated that GS1 Canada's Product Recall accelerated the recall communication process, saved time and improved the overall process efficiency.

Pharmacy: **90%** increase in communication effectiveness, as a result of automatic tracking and reporting of recall receipts.

Manufacturer: Average cost to distribute a recall notice reduced by **\$6,000 to \$8,000**.*

*Manufacturers whose recall process includes sending courier packages.



Manufacturer: **83%** reduction in the time it takes to create a recall notice.

Overall: **80%** reduction in the time it takes to communicate the recall notification from manufacturer to distributor to pharmacy.

Conclusion and Next Steps

Based on the success of the pilots, next steps include national adoption and deployment of the GS1 Canada Product Recall Service by the Pharmacy sector. Opportunities to leverage a standards-based, online communication service are being explored for streamlining communications across the pharmaceutical supply chain regarding adverse drug reaction reporting (Bill C17, Vanessa's Law), as well as reporting drug shortages.