



Complexities of the Drug Supply Chain

A Supplier's Perspective

Sat October 26th, 2024

Craig Potvin
EVP Sales & Marketing
SteriMax

Disclosures

Personal Disclosure

I have the following relationships with commercial interests:

Currently Employed at SteriMax

Speaking Fees for current program:

I have received no speaker's fee for this learning activity

Commercial Disclosure

This program has received no financial or in-kind support from any commercial or other organization

My Background & Experience

Roles/Responsibilities

- Supply Chain
- Distribution
- Contracts
- Sales
- Marketing
- Business Development

Organizations

- SteriMax (Current)
- Leo Pharma
- Fresenius Kabi
- ConvaTec
- Mohawk Medbuy
- HealthPRO

Objectives for this session



Highlight the global and local challenges



Identify the key drivers and top 3 reasons causing shortages in Canada



Provide insights into the complex supply chain



Share some of the actions suppliers are taking to avoid shortages and minimize impact when they occur



Share learnings and opportunities for the industry and Pharmacy community to work together with the goal of improving supply and ultimately patient care

Shortages – A Global Challenge

1 in 3 U.S. hospitals severely affected by drug shortages

- NBC News

Many countries are facing shortages of common drugs.

- The Lancet

Drug Shortages: A Growing Concern for the Healthcare Industry Worldwide

- PharmaNews Intelligence

Drug shortages occur globally, across a range of therapeutic areas, but appear to be mostly centred around the generic and biosimilar markets.

- Napier M., Kourouklis D., Cole A., Cookson G., 2023. The dynamics of drug shortages. OHE Contract Research Report, London: Office of Health Economics.

The issue of low prices in the generic and biosimilar markets appears to be a key driver of drug shortages, often underlying the causes of drug shortages.

- Napier M., Kourouklis D., Cole A., Cookson G., 2023. The dynamics of drug shortages. OHE Contract Research Report, London: Office of Health Economics.

Generic drugs in the US are too cheap to be sustainable, experts say

- The Guardian Jan 2024

Are Generic Drugs Too Cheap for Their Own Good?

Prices are falling despite shortages of lifesaving medications. Something doesn't add up.

- Bloomberg Nov 2023

How rock-bottom prices drive shortages of generic drugs used in hospitals

- NPR Dec 2023

Unique Canadian Challenges

Available manufacturing capacity is often prioritized for larger US and European markets

Canada represents 2-3% of global pharmaceutical market

Approved suppliers don't always maintain inventory

Canadian specific product specifications or regulatory requirements

Limited local manufacturing infrastructure and expertise in entire supply chain (API, raw materials, vials etc.)

Canada's vast geography- Multiple days to ship coast to coast

Drug Shortages is a Serious Concern for Canadians

What are Drug Shortages? The inability to meet demand.

A situation in which the manufacturer to whom a document was issued under subsection C.01.014.2(1) that sets out the drug identification number assigned for the drug is unable to meet the demand for the drug.¹

According to the CPhA drug shortages survey of 1,500 Canadian residents:³

- 69% of Canadians are concerned about drug shortages in Canada
- 25% of Canadians (one in four) have either personally experienced or know someone who has experienced a drug shortage in the last three years

According to the CPhA drug shortages survey of 1,743 pharmacists:⁴

- 79% of Pharmacists indicated that shortages have 'greatly increased' in the last 3-5 years^{2,4}
- 96.1% of Pharmacists indicated that shortages lead to an increase in stress for them
- Drug shortage management generally occupies between 1% and 20% of their time per shift

10% to 15% of Canadian drugs reported in short supply at any given time³



Impact on Patients' health and wellbeing

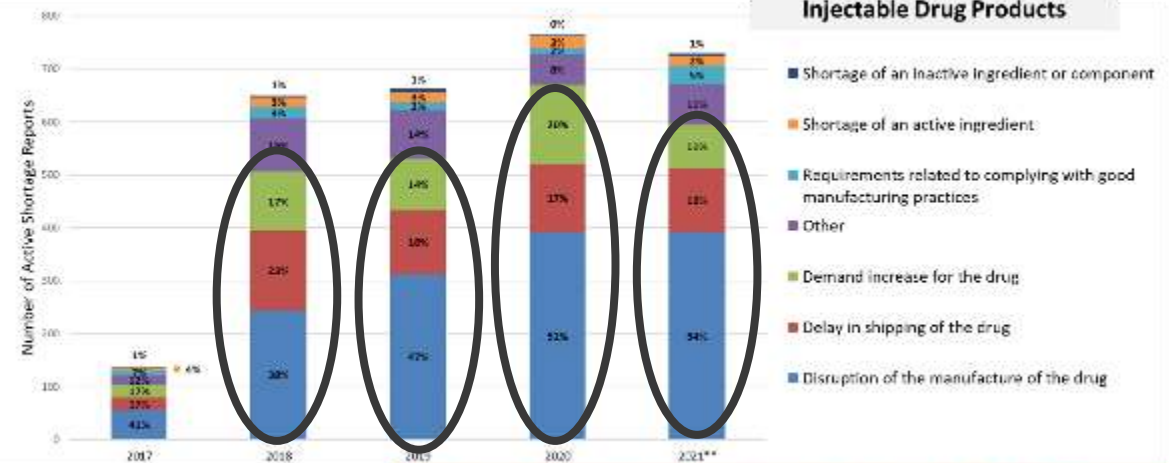


Burden on caregivers, and healthcare providers



Impact of the unavailability of critical essential medicines in hospitals⁹

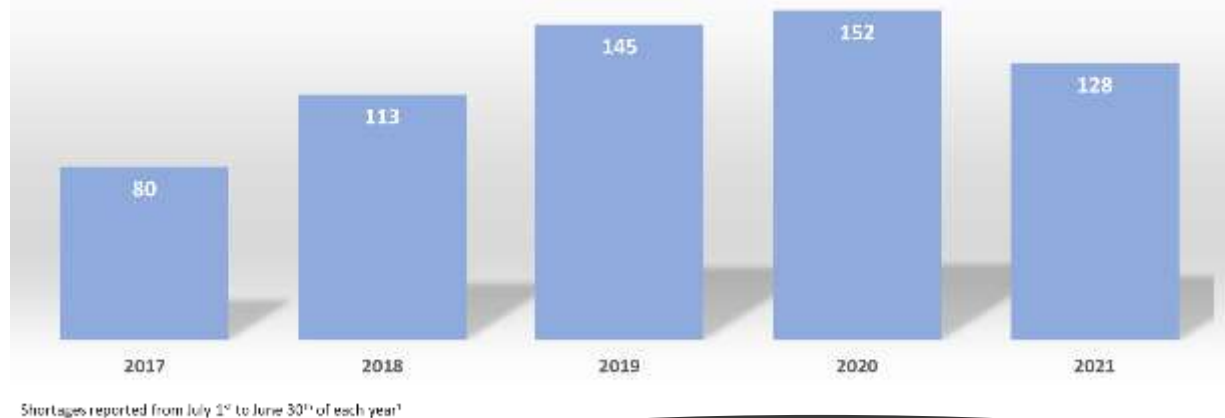
Drug shortage reported for injectable products



Shortages reported from July 1st to June 30th of each year¹
 **2021 does not include 7th and 8th months of 2021 drug shortage reports (June 29th 2021)

Key take away: Manufacturing/Shipping/Capacity are consistent issues for IV shortages

Average Duration of Injectable Shortages (Days) by Shortage End Date



Shortages reported from July 1st to June 30th of each year¹

Key take away: duration of shortages are significant - lasting 4-5 months

What are the main causes of supply shortages?

DRUG SHORTAGES in 2022 to 2023

Reports

In 2022 to 2023, over 2,700 drug shortages were reported.

Companies need to report each time they cannot fully meet the demand for their drug. Not all reports are cause for concern for patients as many of the same drugs are available in different formats or quantities. Most shortages are successfully managed before they impact patients.

2700+
DRUG SHORTAGES
REPORTED

TOP 3 REASONS FOR DRUG SHORTAGES



1
**Manufacturing
problems**



2
**Unexpected
increases in
demand**



3
**Shipping
delays**

Duration

The average length of a drug shortage reported during this period was 98 days.



98 DAYS
AVERAGE LENGTH
OF DRUG SHORTAGES

What drives this challenge and its complexities?

Solutions

Trends

Responsiveness

Capacity

Cost Savings

Efficiencies

Controls

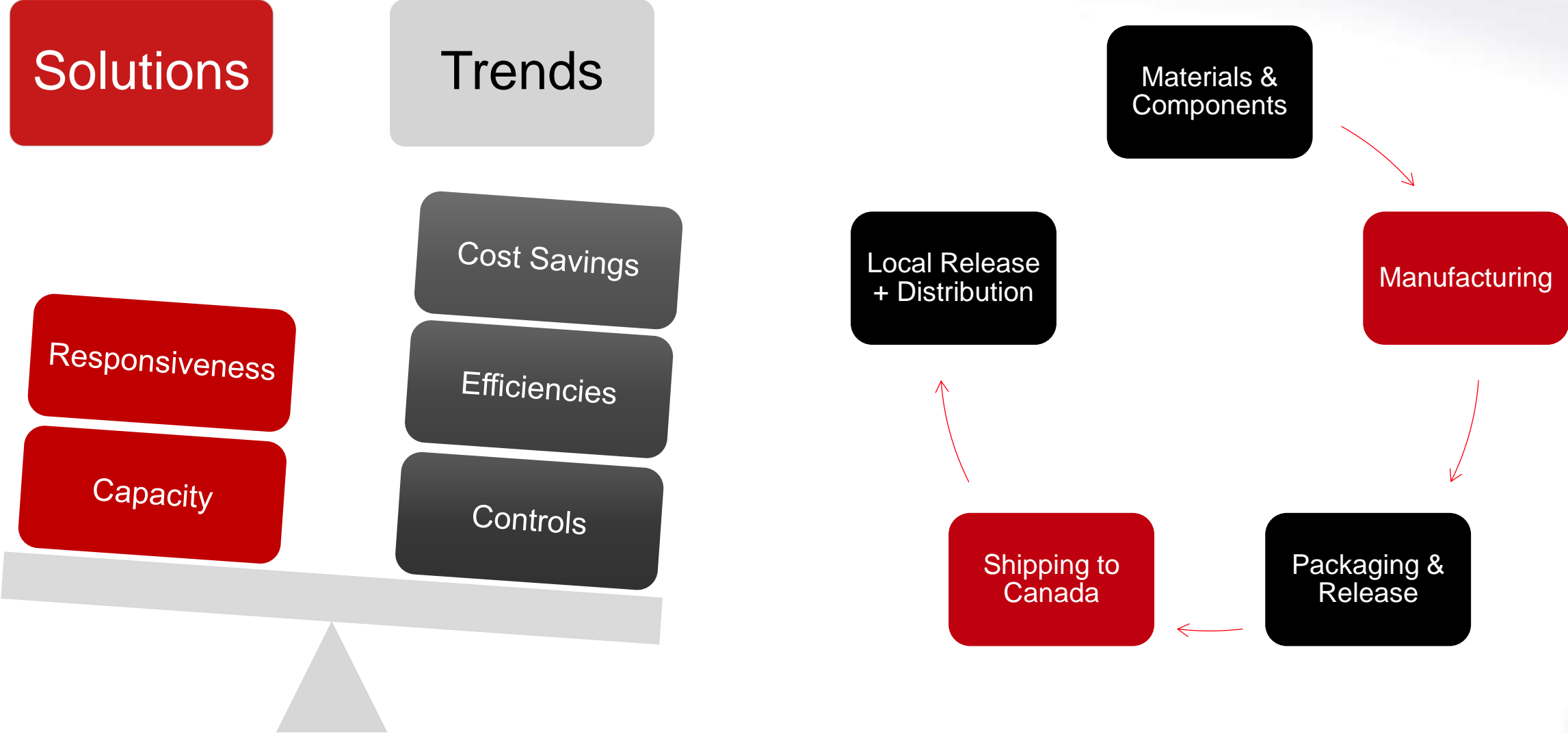
Materials & Components

Local Release + Distribution

Manufacturing

Shipping to Canada

Packaging & Release



Business Models - Manufacturing

Vertically Integrated

- Manufacture 100% of their products at their own facilities

Hybrid

- Manufacture **some** products at their own facilities and others with a partner

Partner/CMO Model

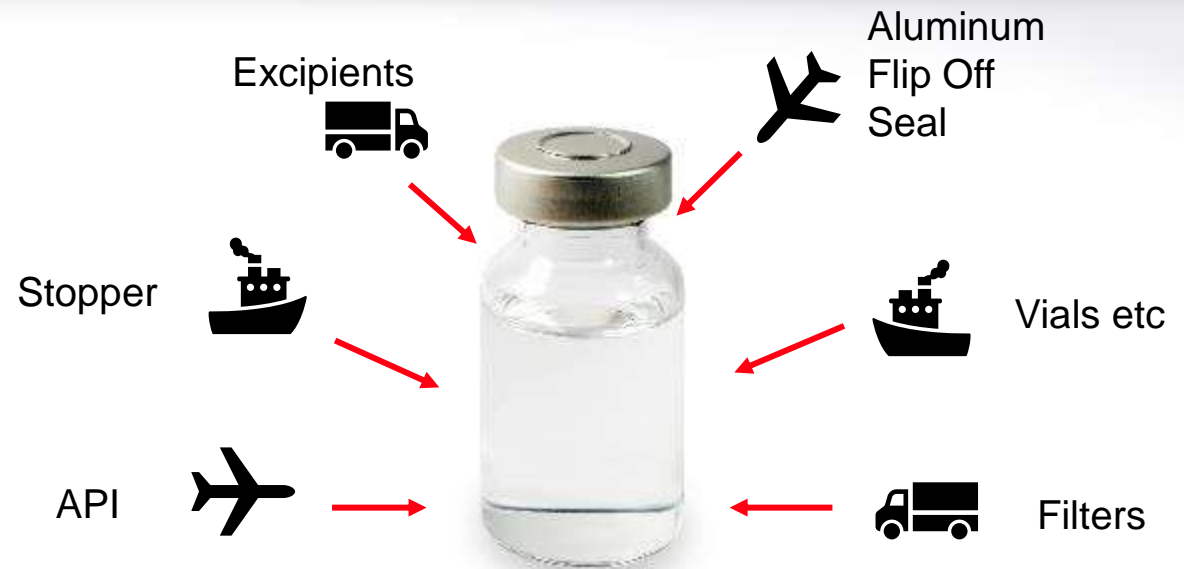
- Have contract relationships with partner(s) to manufacture products

Require outside suppliers for their production and manufacturing

Complex Supply Chains (Manufacturing + Packaging + Release)

Materials and Components

- All necessary components have their own manufacturing lead times and expiry
- They all have their own set of quality standards that must be met
- Many of these are not coming from the same place so a delay in shipping can lead to a disruption
- Can't easily change items (Approval Required)



Manufacturing

- Scrutiny by regulators
- Staffing, capacity available
- Equipment or cleaning procedure issue prior to production



Labels & Packaging



GMP/Qualified
Manufacturing Staff
& Equipment

Manufacturing Release

Manufacture, Packaging, Testing & Release at Manufacturing Site that meets all approved product specifications and GMP

- deviation, failure or OOS during or after production

Complex Supply Chains (Shipping + Release)

Shipping

- Booking & Securing Appropriate Space
- Specialized containers for temperature control
- Air vs. Ocean vs. Ground considerations (environmental, risk, cost)
- Managing temperature and shipping conditions



Up to 2-3 Months for Product to Arrive at Supplier

Businesses face higher trucking costs amid rail labour dispute

The ongoing labour dispute between Canada's largest railway companies and their workers is driving up the cost of shipping by truck, with smaller businesses disproportionately affected.

Rosa Saba, The Canadian Press
Aug 23, 2024 12:30 PM



Canada

Montreal port strike ends, but tensions linger over prolonged strike in U.S.

The Viau and Maisonneuve terminals handle more than 40 per cent of container traffic

The Canadian Press · Posted: Oct 03, 2024 11:00 AM EDT | Last Updated: October 3

Local Testing and Release

- Supplier responsible for the product testing & release
- Document Review, Temperature Monitoring, Testing & Release for Sale

Product Distribution to Hospitals

Direct Distribution

Supplier Warehouse



Distribution Partners

Supplier Warehouse



Canadian Pharmaceutical
Distribution Network
Hospital Direct. Simplified.



MCKESSON

Empowering Healthcare

Product Distributed Across
Canada

3 Distribution Centers



9 Distribution Centers
Across Canada

Let's Recap

- Supply to Canada is a global and complex issue
- Canada has unique challenges that increase complexity + frequency of potential disruptions
- While we understand the key drivers we cannot control the larger global issues but instead we can partner to mitigate their impacts
- **What can we do?**



Suppliers Actions to Reduce Frequency and Length of Shortages

Maintain 6+ months of safety stock for critical products

Redundancy - secondary API sources and/or manufacturing sites

Daily drugshortages.ca review for shortages (proactive response)

Weekly sales/inventory review to detect demand changes early

Transparent and accurate communication of anticipated and actual shortages

How Can Suppliers Mitigate Shortages?

Preventative Allocations – Internal + Distributors

Work with Split Award partner and alternate suppliers

Work closely and promptly with manufacturing partners

Tier 3 Importation utilizing global network

Open, proactive & consistent communication

Takeaways.... How can you help prevent Shortages?

**Share planned alternate
therapies to prevent new
shortages**

**Check with supplier if
there is no product at
local distribution center**

**Timely communication of
practice changes that
could impact demand**

**Orders can be filled and
drive supply... planned
orders can't**

A close-up photograph of a healthcare professional in a white lab coat holding a patient's hand. The professional's stethoscope is visible around their neck. The patient's hand is resting on a white surface, possibly a table or bed. The background is softly blurred, showing more of the professional's coat and the patient's arm.

**It's complex but the more we understand
and work together the better the
outcomes for Canadian Patients**

Thank You!