

# Cancer Drug Shortages: System Lessons from Recent Cases

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## Ripple Effects on Healthcare System

- Cancer Care Ontario (CCO) is the provincial advisor to the Ministry of Health and Long-Term Care (MOHLTC) on cancer drug policies, including issues related to drug supply interruptions (“shortages”).
- Shortages have extensive implications on the healthcare system, challenging standard clinical practices, disrupting hospital workflow, and potentially compromising the delivery and quality of patient care.

## CCO’s Purpose

- Shortages can occur for various reasons and are often originated at the supply chain level.
- Unlike many provincial cancer agencies in Canada, CCO is not directly involved in the procurement and management of local cancer drug supplies.
- In the event of a cancer drug shortage in Ontario, CCO aims to provide strategic directions and clinical guidance for Regional Cancer Centres and affiliated hospitals to ensure patients across the province are managed consistently and appropriately.

## Objectives

- Our objective is to evaluate the management of three cancer drug shortages in Ontario and identify opportunities to:
  - Minimize patient impact
  - Minimize administrative burdens on front-line providers
  - Improve timeliness and preparedness
  - Overall mitigate or minimize disruption to the health care system
- We reviewed three cancer drug supply issues that occurred in 2014. Table 1 is a summary of the issue origins, management strategies, logistical challenges, levels of stakeholder engagement, and the overall impact on hospital workload and the quality of care for affected cancer patients across the province.

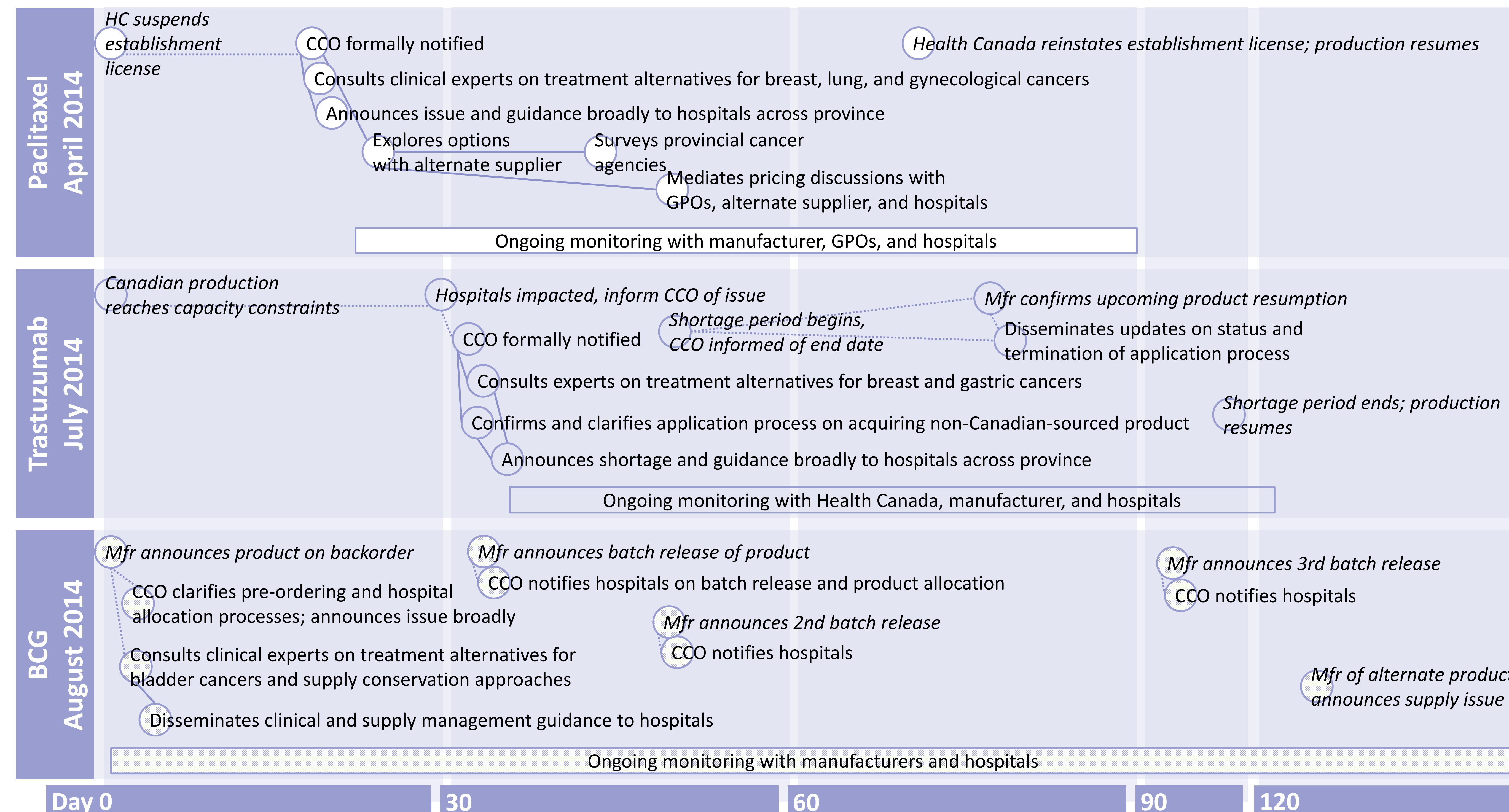
## Three Recent Cancer Drug Interruptions in Ontario

Drug	Origin of Issue	CCO’s Primary Management Strategy	Challenge(s) in Issue Management	Level of Stakeholder Engagement Required					Level of Impact on Hospitals & Cancer Centres	Potential Level of Impact on Patients		
				HC	Mfr	GPO	Exp	Hosp				
<b>Paclitaxel</b>	Revocation of a Canadian establishment license	Facilitate ability for hospitals to acquire product from an alternate supplier	Addressing competitive pricing in acquiring drug from alternate manufacturer	○	●	●	●	●	●	●	<ul style="list-style-type: none"> <li>• Unexpected financial strains on hospital budget</li> </ul>	<ul style="list-style-type: none"> <li>• Delay in care</li> <li>• Incurring out-of-pocket expenses</li> </ul>
<b>Trastuzumab</b>	Canadian supply constraints	Coordinate with Health Canada to facilitate acquisition of foreign supply	Establishing mitigation strategy in a timely manner for a finite shortage period	●	●	○	●	●	●	●	<ul style="list-style-type: none"> <li>• Increased staff workload on processing requests to HC for individual patients</li> </ul>	<ul style="list-style-type: none"> <li>• Delay in care</li> </ul>
<b>Bacillus Calmette-Guérin (BCG)</b>	Global supply shortage	Develop guidelines on clinical alternatives and patient management	Coordinating of consensus amongst clinical experts on alternate treatments	●	●	○	●	●	●	●	<ul style="list-style-type: none"> <li>• Increased staff workload on reprioritizing treatments</li> <li>• Changes to standard clinical practice</li> </ul>	<ul style="list-style-type: none"> <li>• Delay in care</li> <li>• Sub-optimal effectiveness from alternate treatment</li> <li>• Subsequent shortages affecting increased number of patients</li> </ul>

**Table 1.** Three cancer drug interruptions in 2014 that impacted hospitals and patient care across Ontario. **HC:** Health Canada, **Mfr:** Drug Manufacturer, **GPO:** Group Purchasing Organization, **Exp:** Clinical Experts, **Hosp:** Hospitals. **Level of engagement or impact from low to high:** ○ ● ● ● ●

## CCO’s Advisory Role in the Management of Three Recent Interruptions

No two scenarios are alike. All shortage issues differ in origins, magnitudes of impacted stakeholders and patients, and management/mitigation strategies. The figure below illustrates CCO’s facilitation and coordination efforts in managing the paclitaxel, trastuzumab, and BCG supply interruption events. Each series of events is plotted on a timeline, where Day 0 represents when the issue was initiated. Events in italics and connected in dotted lines represent key events that influenced CCO’s management strategies.



## Lessons Learned

The SWOT analysis below assesses CCO’s strengths and weaknesses in managing shortages based on recent experiences. The analysis also identifies opportunities and threats from minimizing patient impact and disruption to the overall healthcare system.

Strengths	Weaknesses
<ul style="list-style-type: none"> <li>• Established working relationships with drug supply chain stakeholders</li> <li>• Access to clinical disease expertise for immediate attention</li> <li>• Ability to manage immediately reimbursement issues that emerge from shortages</li> </ul>	<ul style="list-style-type: none"> <li>• Decentralized drug procurement and purchasing system</li> <li>• Lack of procurement control limits CCO’s ability to mitigate allocation and price issues</li> <li>• Lack of distribution and regulatory controls places onus directly on front-line providers and hospital administrators</li> </ul>
Opportunities	Threats
<ul style="list-style-type: none"> <li>• Explore issues &amp; understand timelines with manufacturers</li> <li>• Mandate early notifications on impending shortages</li> <li>• Leverage existing approaches by other provincial agencies</li> <li>• Collaborate with manufacturers, regulatory bodies, and hospitals to improve preparedness and timeliness in handling shortages</li> </ul>	<ul style="list-style-type: none"> <li>• Delayed notification from manufacturer affects CCO’s ability to notify hospitals and implement mitigation strategies</li> <li>• Increased workload on hospital staff impacts quality of patient care</li> <li>• Variable approaches in clinical management across the country may lead to patients receiving inconsistent care</li> </ul>

## Next Steps

- Compare Ontario’s management approach and outcomes with other provincial jurisdictions.
- Validate with proposed national approaches and guidelines issued by the Canadian Association of Provincial Cancer Agencies (CAPCA).
- Encourage regulatory bodies (Health Canada) and manufacturers to understand the impact of drug shortages on the overall healthcare system.