Multi-Stakeholder Committee on Drug Shortages

Guidance Document to Mitigate Drug Shortages through Contracting and Procurement

Revised in 2017

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FOREWORD

The Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) was assembled in 2012. The MSSC includes representatives of industry associations, federal, provincial and territorial governments and health professional associations, coming together to address drug shortages in a collaborative and coordinated manner. The MSSC recognizes that drug shortages are a complex, global problem involving all stakeholders across the drug supply chain.

In 2013, the MSSC created two important resources for understanding and mitigating drug shortages in Canada. The MSSC *Multi-Stakeholder Toolkit* describes the Canadian drug supply chain, clarifies roles and responsibilities, and identifies tools and strategies to address drug shortages. The *Protocol for the Notification and Communication of Drug Shortages* sets out clear expectations for the notification and communication of information in anticipation of or in response to a drug shortage. Together the Toolkit and Protocol establish a common understanding and expectations to support coordinated multi-stakeholder communication and engagement to counteract, mitigate and manage drug shortages in Canada.

In addition to establishing an effective responsive communication protocol for use *during* drug shortages, it is important to identify supply chain tools and actions that might help *prevent* and *mitigate* drug shortages. Health care providers use *contracts and the procurement process* to communicate expectations to suppliers and distributors on drug supply needs. Supply contracts are fundamental for ensuring Canadians have access to a consistent, reliable and safe supply of medically necessary drugs.

This report has been prepared by the MSSC, to provide best practice guidance to Canadian drug supply chain stakeholders. It identifies supply chain vulnerabilities that can arise under conditions of scarce supply along with contracting and procurement practices that may prevent, mitigate and manage the vulnerabilities inherent in a complex, dynamic supply chain.

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INTRODUCTION

Many of the medicines used by Canadians to treat aches and pains, manage acute and chronic diseases, as well as severe life threatening conditions, are produced globally, and arrive in Canada through a long and complex process. At each step of this process, a drug is procured by one stakeholder and then passed along the supply chain to the next. In most cases, their business relationships are governed by procurement contracts.

At the end of this intricate supply chain, Canadian patients and their health care practitioners are experiencing more occurrences of supply-based shortages of their essential medicines and disruption in the delivery of their care. This is problematic as the wellbeing of many Canadian patients is contingent upon the ability to access a consistent, reliable, and safe supply of medically necessary drugs.

To help address the procurement aspect of this problematic trend, a representational multi-stakeholder group was assembled, to work collaboratively in an effort to identify best practices that would prevent, mitigate and manage the supply of all available drugs in each step of the healthcare supply chain. The group also determined which key stakeholders could support and contribute to the outcome of the timely coordination of mitigation measures to enable health care practitioners and their patients make timely and well-informed decisions.

Although the business interests of the stakeholders assembled differed, a common thread brought the group together – the best interest of the patient.

This guidance document has been prepared as a resource to improve understanding of Canadian drug supply chain vulnerabilities related to drug shortages and to provide related best practice guidelines for drug contracting and procurement strategies.

In order to arrive at best practice guidelines, the following questions were considered:

- What key stakeholder groups are involved in contracting and procuring drug supply for Canadians?
- What are the core contracting and procurement activities of these stakeholder groups?
- What vulnerabilities and risks can arise in these activities, particularly in conditions of scarce supply?
- What contract or procurement strategies and activities can be used to reduce the vulnerabilities and prevent or mitigate the risks?

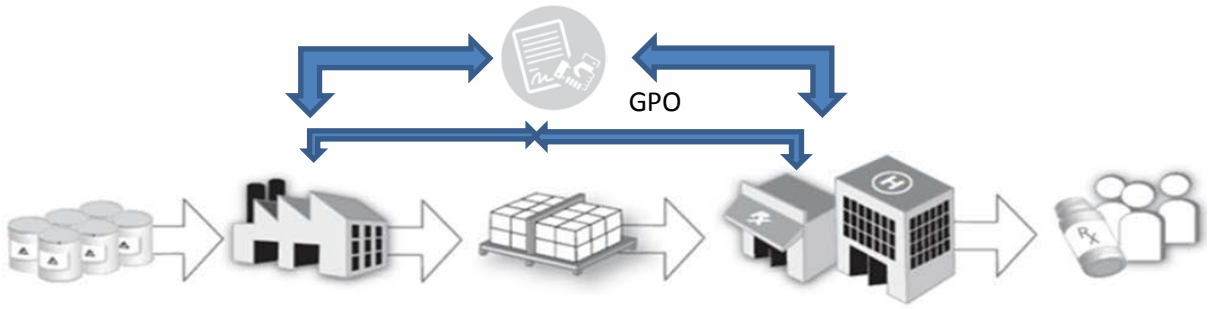
Five primary supply chain conditions were identified that can introduce vulnerabilities and impact the effectiveness of the Canadian drug supply chain. The guidance document describes each condition, identifies specific vulnerabilities introduced by it and outlines contracting and procurement remedies

that can be used to reduce the associated risks. These remedies can be applied at different points in the supply chain by different stakeholders, all with the common goal of assurance of supply.

The guidance document further outlines best practice contracting guidelines, procurement strategies and tools, which can be applied by and negotiated between various stakeholders. The tools outlined have been formulated to support and contribute to a consistent, reliable, efficient and safe supply of drugs for Canadians.

Best practice tools and strategies continue to emerge to address drug shortages across the Canadian health care system. This guidance document offers best practices (i.e. practices which have been demonstrated to be effective, leading practices which have shown promising results, and emerging concepts and principles,) which can guide stakeholders in the drug supply chain for continued collaboration toward improved results. The concepts and practices are not intended to be prescriptive.

Key Stakeholder Groups:



1 SUPPLY CHAIN CONDITIONS, VULNERABILITIES AND REMEDIES

Understanding supply chain vulnerabilities is the essential first step to identifying contracting and procurement practices that may mitigate or prevent drug shortages. This section of the report provides a summary of key conditions that introduce vulnerabilities as well as contracting and procurement and broader supply chain remedies that can be applied to reduce risk. Contracting and procurement remedies can be implemented through the contract holder/supplier business relationship, while broader supply chain remedies require the involvement and action of additional supply chain stakeholders and therefore are beyond the scope of contracting and procurement best practices. A summary of Broader Supply Chain Remedies is provided in Appendix B.

Based on a detailed analysis of supply chain stakeholders, their core contracting and procurement activities, and related vulnerabilities, five primary conditions that introduce vulnerabilities in the global supply chain were identified:

1. Globalization of Drug Supply Industry
2. Complexity and Responsiveness
3. Distribution and Inventories
4. Quality and Price
5. Procurement Practices

The process of identifying vulnerabilities is to first identify and understand, and then to collaboratively manage the associated risks within the Supplier community. For instance, if a medicine has a short shelf-life (short-dated), that is the nature of the product. Its short-dated nature presents vulnerability if the supply chain (due to length or complexity) cannot always ensure the product is available to the end user with a significant amount of its shelf life remaining. Also, supply chain processes and regulatory parameters are realities of the Canadian drug supply system, and need to be taken into account when circumstances require rapid adjustment to changes in supply and demand. Understanding these factors allows for the identification of appropriate contracting and procurement best practices to reduce potential risks.

1.1 GLOBALIZATION OF DRUG SUPPLY INDUSTRY:

The drug supply industry serves global markets and achieves efficiencies by concentrating costly manufacturing in strategic global locations. Pricing pressures, market dynamics, and competition in the market have led to consolidation of suppliers and product lines. Current market conditions favour global manufacturers and suppliers, resulting in fewer options for end customers.

Vulnerabilities related to Globalization:

- Most of the manufacturing and supplier organizations servicing the Canadian market also serve other national markets. Canada's total consumption of drugs represents 2-3% of the global market. The Canadian supply chain could be seen as a lower priority to manufacturers and difficult to serve due to its relative size. Canada must take its place in the global network of supply chains serving multiple markets resulting in a supply chain which is longer and less

flexible. Suppliers may serve larger markets preferentially when supply diminishes. Nonetheless, Canada remains the eighth largest global market and should leverage this position

- Global supply chains are regularly reconfigured as decisions affecting product line viability, discontinued products, inventory allocation and plant closures, are based on the impact to the bottom line of the global business, not based on Canadian clinical practice or local conditions
- Supply Chains have become more susceptible to failure as global manufacturing sites may be the only source of supply. This single source of supply is then vulnerable to actions of any foreign regulator or adverse event which may result in reduced capacity
- Proliferation of new product lines without corresponding increase in production capacity

International regulatory bodies (e.g. Health Canada, U.S. Food and Drug Administration, European Medicines Agency) continue to expand their scope of oversight, including extending Good Manufacturing Practices (GMP) requirements for Active Pharmaceutical Ingredient (API) suppliers. When an API supplier, who is the source of supply for multiple manufacturers around the globe, fails to comply with GMP requirements, and must reduce supply, or close their plant, there can be a resulting lack of supply that starts at the beginning of the supply chain and cascades in a domino effect throughout the global supply chain, affecting many countries, and many end users.

Contracting and Procurement Remedies:

- Require suppliers to provide appropriate notification and communication to contract holder of events along supplier's complete global supply chain that would have a negative impact on the Canadian market
- Ensure suppliers demonstrate diversity in their global supply chain or have capacity to create diversity through contingency plans (i.e. have more than one source of API, or have more than one format. Or have excess capacity)
- Require suppliers to establish and maintain appropriate levels of safety stocks throughout the Canadian supply chain to ensure the supply chains are robust and nimble
- Require suppliers to guarantee safety stock levels through the segregation of safety stock to meet the needs of consuming organizations
- Ensure the appropriate level of controls and information sharing is in place to ensure safety stock levels are adjusted appropriately as supply chain configurations are adjusted
- Establish supply contracts to ensure a commitment to supply from global organizations

Broader Supply Chain Remedies:

- Increased knowledge of viable alternate global sourcing options in the event of a shortage in Canada of a critical drug
- Segregation of safety stock by each end user (consuming organization) to ensure security of supply to support their needs. This will impact the efficiency and cost of procurement

1.2 COMPLEXITY AND RESPONSIVENESS:

The systems and processes in the drug manufacturing industry, for both sterile and non-sterile manufacturing, are complex and time-intensive. For example, product development and construction or modification of sterile manufacturing facilities have a time scale and planning cycles measured in years. Production planning for sterile products and specialty manufacturing has a time scale measured in half-years. Regulatory processes and procedures for review and approval of sterile and non-sterile product submissions and establishment licences have a time scale also measured in half-years. The linkages between various processes and timelines need to be carefully managed to minimise or address shortages. The production and distribution of products that are fragile and may require special handling, or that have short shelf-life have an even higher level of complexity and require a more intense management.

All these features challenge the system to be responsive to shorter term disruptions in supply.

Vulnerabilities related to Complexity and Responsiveness:

- The supply chain takes a long time to respond to unforeseen short-term market changes (e.g. increased local demand, or cascade impact of other local shortages)
- Any unforeseen production disruptions to highly organized and complex systems may have negative consequences on the whole system
- Capacity for sterile manufacturing is limited and any reductions in that capacity, whether resulting from production, business decision or other disruptions, may adversely affect the whole system
- Business or production problems may require a long time to remedy i.e. with API suppliers
- Reliance on a single source of product, component or production facility within a complex system impedes the ability to quickly respond
- A supplier's ability to establish alternate supply responses to a drug shortage can take longer than the duration of the shortage. In addition, once the "normal" supply chain recovers, alternate suppliers can be left with unrecoverable costs and inventory. These factors discourage alternate suppliers from responding to drug shortages.

Contracting and Procurement Remedies:

- Identify the areas of risk in the production cycle (i.e. where the timeframe of a production remediation plan will likely result in a disruption of supply) and establish a contingency plan
- Put in place notification and communication time scales that correspond with the time scales of remediation plan
- Provide notification of all high risk actions that may trigger a supply disruption at any step in their own or a business partner's supply chain
- Share contingency plans amongst all stakeholders
- Notify and communicate with contract holder when contingency plans are triggered
- Contract with multiple suppliers for the supply of a product
- Identify alternate formats and therapeutic alternatives on www.drugshortagescanada.ca

Broader Supply Chain Remedies:

- Contract holders collaborate on national identification of critical, high priority products for which a higher specified level of performance is required

1.3 DISTRIBUTION AND INVENTORIES

Current supply management practices were not designed to accommodate or be adapted to address shortages and supply disruptions.

The **global** drug supply chain can be quite long involving many stakeholders in many countries including global raw material providers, global manufacturing sites, global packaging sites, local suppliers' distribution sites, local distributors, local retail and public health care outlets.

Suppliers normally maintain safety stock to support their global processes and respond to unplanned production problems. Safety stock is generally not sufficient to accommodate planned reductions in capacity initiated in response to a production issue, or unplanned increased demand from the cascade effect of shortages in the competitive market.

The **local** drug supply chain is comprised of the supplier's direct supply channel, logistics providers, wholesalers, distributors, and health care provider delivery locations. The supply chain is, for the most part, a push system with a whole set of unconnected systemic delays, lags and constraints. Most stakeholders are business operations driven by business imperatives. Each stakeholder, including retail and institutional pharmacies, has taken steps to maximise efficiencies and returns for their particular section of the supply chain, not the supply chain as a whole. Ultimately, some stakeholders work on a Just-in-Time business model with attempts to minimize inventory holding. This makes the whole supply chain susceptible to overages and shortages when there is a minor variation in demand.

Significant problems at any point along the supply chain can cause disruptions that reverberate along the rest of the chain. When disruptions are significant, extended or related to critical products considerable strain is placed on the system.

With current practices, no stakeholder has the capacity or resiliency to absorb the impact of large disruptions. The agility, flexibility and foresight that would be needed to mitigate the impact of large or critical drug shortages do not currently exist in the system. As there is no one "owner" of the supply chain, no organization can on its own identify, resolve and balance these systemic issues.

When there is disruption in the local supply chain, the upstream global supply chain finds it difficult to respond in a time frame adequate to the need.

Furthermore, in spite of advancements made through the efforts of the MSSC, when shortages occur the lack of coordination and clear accountability makes the response to the shortage difficult to manage and potentially chaotic. This can result in hoarding or the imposed allocations that impact patients that have clinical need for the product.

Vulnerabilities related to Distribution and Inventories:

- Lack of accurate, up to date information on inventory levels across the drug supply chain
- Low inventory levels throughout supply chain
- Excessive reliance on distribution provider and on single distribution provider
- Industry use of third party for distribution between suppliers
- Complications in re-locating inventory within the supply chain
- Allocation process is sub-optimal and difficult to manage
- Lack of control for excessive inventory purchasing which allows hoarding
- Unpredictable increased demand for alternate products causes cascade effects
- Poor flow of information throughout the supply chain leads to costly errors. For example, information on whether the situation is a stock out or a shortage is crucial but often difficult to obtain
- Impact of widespread shortages has made historic usage information inaccurate and unreliable

Contracting and Procurement Remedies:

- Increase visibility of all stock levels in the supply chain.
- Segregate and guarantee safety inventory
- Add diversity in distribution channels and inventory locations

Broader Supply Chain Remedies:

- Stakeholders across the drug supply chain make up to date information about demand, sales forecasts, inventory levels and stock replenishment orders visible to all participants in the supply chain.
- Commit to increased inventory holding throughout the supply chain at manufacturer, distributor, and retail and institutional pharmacy sites
- Each key stakeholder in the local supply chain establishes appropriate levels of safety stocks consistent with the local end-user and distribution requirements
- Improve standardized allocation process through normal distribution channel
- Impose limitations on purchases and alerts for unusual purchasing activity
- Improve national sales data to support better forecasted inventory holdings
- Implement a process for health care providers to notify suppliers and distributors of alternate therapy plans during a shortage or changes to normal practice which would affect inventory needs
- Industry stakeholders adopt national standards for tracking and tracing inventory

1.4 QUALITY AND PRICE:

Quality and safety of products for Canadians is paramount and cannot be compromised. The quality, safety and efficacy of drug products and minimum labelling requirements are regulated by Health Canada and products marketed in Canada must meet these requirements.

Pharmacy practitioners apply and continually refine safe medication practices using resources and guidance from the Institute for Safe Medication Practices (ISMP Canada) to identify packaging and labelling quality requirements that will promote medication safety and reduce errors. These expectations are communicated to suppliers and have a significant impact on procurement practices in Canada.

Quality of supply means ensuring the availability of drug products to Canadian patients at all times, in adequate amounts, in the appropriate dosage forms, at a price the individual and the community can afford.

In some cases, there can be a misalignment between the business goals of suppliers and the social, medical and economic requirements of health care providers. Those responsible for contracting and purchasing drugs for health care providers often seek best value in the market as they are stewards of the health care dollars entrusted to them. Suppliers compete to attain market share of the business and they compete on price and service to meet the needs of the health care buyers as communicated to the market in the competitive proposal documents.

The quality of production and its weighting on the ability of suppliers to compete in the current marketplace has only recently been recognized as an important component of the competitive bid process for generic sterile products. Health care professionals recognize the cost associated with the disruption of supply within the health care system, especially when adequate planning and/or contingency plans have not been formulated.

Vulnerabilities related to Quality and Price:

- Suppliers may respond to downward price pressure and increasing quality expectations by exiting the Canadian market for that product only, or for all of the suppliers products in Canada
- Health care system impacts and negative consequences as a result of product scarcity and shortage can be significant.

Contracting and Procurement Remedies:

- Request for competitive proposal documents that clearly include recognition of quality of supply to ensure the appropriate balance between the price of product, and the ability of the supplier to reliably provide a quality product
- Suppliers become more transparent about their business practices to ensure their quality of supply can be adequately and fairly assessed by health care buyers in a competitive proposal process and post contract award. Information could include frequency of batch failures at

manufacturing facility, regulatory compliance status of manufacturing sites, inventory locations and days on hand standards for these inventory locations.

- Contracts include incentives for quality of supply or the request for competitive bid weighting indicates a preference based on a supplier's quality of supply

1.5 PROCUREMENT PRACTICES

Traditional contracting practices based on stable local Canadian market conditions have inadvertently contributed to the disruptions in the quality of supply of drug products. Changes in contracting practices have not kept pace with changes in the production and supply of drug products, limiting their effectiveness in mitigating drug shortages.

Health care procurement professionals and retail pharmacy buyers need to strategically invest in procurement practices that will drive leading practice and restore supplier and product diversity to better meet and manage a dynamic market and supply chain challenges.

Vulnerabilities related to Procurement Practices:

- Single-award practices, when multiple potential suppliers exist, may eliminate competition resulting in loss of suppliers and capacity from the marketplace
- Competitive proposal practices favouring price with a limited consideration of supplier historical quality and reliability may encourage a continued downward spiral in supply chain performance thereby increasing potential for more shortages
- Supply contract cycles, while providing supply security, create barriers to entry of alternate suppliers as these alternate suppliers are locked out of marketplace for a long period of time
- There may be resistance to change in health care sourcing practices and supplier openness

Contracting and Procurement Remedies:

- Implement contracting processes that favour suppliers who demonstrate the ability to reliably provide product with minimal threat of shortage
- Health care procurement professionals and retail pharmacy buyers create
  - Improved systems and practices to provide better forecasts of demand to suppliers
  - A Canadian environment that maintains and encourages diversity of supply while increasing the quality of supply
  - Incentives that reward positive supply chain outcomes and encourage supplier innovation for assurance of supply
  - Increased variety of available procurement options to reach goals of procurement process including entry and exit strategies during regular contract or during shortage crisis
- Health care procurement professionals and retail pharmacy buyers encourage diversity of supply by opening opportunities for suppliers interested in entering the Canadian market through approaches such as forward contracting

1.6 CONCLUSION

There are many remedies that can be brought to bear on the major vulnerabilities in the supply chain. The key goals to help guide selection and implementation of remedies are:

- Greater diversity along the supply chain - in production, distribution, number of contracted suppliers
- Greater capacity in production and inventory holding - increased availability and visibility of safety stock throughout the supply chain, including the supplier upstream, to better absorb unexpected disruptions in supply
- Greater transparency and understanding between stakeholders - sharing of critical information regarding production challenges and therapeutic requirements so all stakeholders can create aligned and effective contingency plans to accommodate weak links
- Greater advanced notification and communication - of potential planned and unplanned shortages, within the response timeframe of the global supply chain, for appropriate action to be taken

A summary of broader supply chain remedies that represent important solutions yet are beyond the scope of the Working Group mandate can be found in Appendix B.

The following section outlines best and leading contracting practices that support these important goals and address the identified vulnerabilities.

2 CONTRACTING AND PROCUREMENT LEADING PRACTICES

Supply contracts communicate current and future drug supply needs and formalize expectations and commitments between health care contracting organizations and suppliers.

Although drug shortages are not new, severe shortages of significant scope and duration are a relatively new experience in the Canadian health care market and, as such, experience with creating and implementing contract best practices to address shortages is emerging. Best practices might include approaches that have a proven record of success, while leading practices may be newer approaches that have demonstrated promise in some organizations, other jurisdictions or other industries. Acknowledging the desire for manufacturers to maintain a competitive position through protection of proprietary information, supply chain stakeholder collaboration and negotiation will help propel further innovation and discovery of best practices for addressing drug supply vulnerabilities.

This section outlines core concepts, best and leading contracting practices for effective procurement of drug products in a dynamic marketplace, primarily focusing on those aspects aimed at reducing the patient risks and significant cost and operational impact caused by drug shortages.

The concepts and practices in this section are not intended to be prescriptive, but rather to provide stakeholders important factors and methods to consider when negotiating supply contracts and procuring drugs in Canada. The competitive selection process may include some or all of the concepts included in this document.

Appendix A provides a more detailed Template for Supply Contract Practices to Reduce Drug Shortage Risk.

2.1 PRELIMINARY QUALITY REVIEW AND PERFORMANCE INCENTIVES

See Appendix A: Section 1

The buyers for institutional and retail pharmacies develop a strategy for the approach to the market which includes:

- An assessment of competitive market conditions including diversity of supplier and product.
- Demonstrated quality performance of supplier for:
  - Quality of manufacturing (GMP: Good Manufacturing Practices)
  - Quality of supply, and
  - Quality of performance during a shortage
- Stratification of goods for potentially different contracting strategies including:
  - Multi supplier awards, (for critical or high volume drugs) i.e. split awards whereby each supplier provides the product, and with sufficient notification is expected to supply the entire customer base if required; should neither supplier be able to meet the demand, only then will either supplier have liabilities and only for their agreed upon market share
  - Inventory Management Agreements with distributors or suppliers
  - Potential secondary supplier awards

- Single supplier awards
- Sole source agreements

- Consideration of where incentives or pay for performance differentials may apply
- Consideration of forward contracting to encourage supply diversification
- Consideration of therapeutic alternatives for drug shortage contingency plans

2.2 COMMITMENT TO SUPPLY

See Appendix A: Section 2

The supplier commits in the contract to take all measures reasonably necessary to supply sufficient quantity of a product to meet, at all times, an amount required for the needs of the institutional or retail pharmacy's (contract holder's/buyer's) patients. This includes agreed to levels of safety stock at the contract holder's/buyer's defined location(s). The supplier commits in the contract, in conditions of threatened or actual shortage, to employ resources from their full global supply chain to meet contract obligations.

The supplier commits to disclose the following:

- when they are unable to meet the entire obligation, in which case the contract holder/buyer is able to seek alternate sources
- when real risks exist in its supply chain which might prevent the supplier from meeting its obligation, permitting the contract holder/buyer to assess whether the risk and the supplier contingency plan for the risk are acceptable
- information on sales forecasts, inventory levels and locations, status of replenishment orders, and tracking of actual demand against forecast
- Participation in and publishing of regular performance reviews

2.3 SECURITY OF SUPPLY - GENERAL

See Appendix A: Section 3

The supplier commits to management and operation practices that will reduce the likelihood of a shortage and ensure:

- Supplier has available capacity:
  - To provide, at all times, sufficient stock to meet customers' needs
  - To increase production of a product with an agreed upon notice period and time frame should it be necessary
- Supplier maintains agreed levels of safety stock based on:
  - Contract holder risk designation of product, supplier production schedule and reliability, product shelf life, or
  - Risk designation of products based on having any single source component at any step of the manufacturing process
- Supplier has and provides business continuity plans and supply continuity plans that protect against disruption and:

- Include critical products under contract
- Include products with supplier single source components
- Include an allocation process whereby the customer may procure products through normal distribution channel with minimal change to standard order placement process
- Are tested annually

- Supplier has the ability to:
  - Guarantee and segregate contracted customer inventory as part of safety stock while supporting 'fair share' access to medically necessary drugs
    - For products identified by the customer
    - In more than one location within a distribution centre, in more than one distribution centre and with more than one distributor, wherever possible or practical
  - Ensure reasonable availability of inventory at all times that is protected through the normal distribution channel including ensuring the ability to identify and control excessive draw from inventory
  - Control movement of inventory and customer access to inventory, including short dated stock, throughout distribution channel

2.4 QUALITY ASSURANCE

See Appendix A: Section 4

The supplier commits to communicating in a timely way when any quality assurance events occur that have reasonable potential for supply disruptions including any regulatory actions by ensuring:

- Supplier adopts a protocol that triggers product specific contingency plans for any reasonable potential supply disruption or expected supply disruption. The protocol includes:
  - Notification and ongoing communications until the supply is restored with the contract holder/buyer:
    - Within specified notification time frame for planned supply disruptions, including discontinuation of product
    - As soon as is known for unplanned supply disruptions, including recall of products
  - Notification and updates posted on www.drugshortagescanada.ca
  - Implementation of remediation plan
- Immediate implementation of an allocation plan through the normal distribution channel, to manage existing inventory
- Supplier provides the contract holder/buyer with prompt notification of any early warning events which may indicate quality assurance problems including:
  - Notification of significant issues cited during regulatory authority action, inspection, or interaction
  - Notification regarding any warning letters received
- Supplier notifies contract holder/buyer of any quality assurance events listed above which may have occurred with:
  - Any upstream suppliers, subcontract holders, or API suppliers

- Products where any single source contingency plans have been triggered

2.5 SECURITY OF SUPPLY - SHORTAGES AND RECALLS

See Appendix A; Section 5

When a shortage or period of restricted supply arises, there needs to be clear understanding amongst the parties as to how the shortage will be managed. Alternate product suitability is based on the fact that a specific strength, dosage form, and route of administration are critical for the targeted needs of the affected patients. The alternate product may be a direct substitute or an acceptable substitute of the same molecule of the drug in a different format subject to approval of the contract holder/buyer.

The entry into the supply chain of an alternate product needs to be carefully managed in each pharmacy to maintain patient safety. The same management needs to apply when the shortage is resolved and the original product is re-introduced into the supply chain. Where alternate contract supplier arrangements exist, the process must be managed to ensure patient safety. The contract holder/buyer and primary supplier will establish defined penalties.

The supplier commits to active and timely management of shortage and recall conditions by working with the contract holder/buyer to identify and secure alternate supply through:

- Supplier and contract holder/buyer shortage management strategies, in order of escalation, including:
  - The contracted supplier may -offer a substitutable product from their product portfolio. The substitute product must be approved by the contract holder/buyer. The supplier will provide the acceptable substitute product at no additional cost to the contract holder/buyer, including factoring in reasonable wastage
  - The contingency plans that the contract holder/buyer has established with other contracted suppliers may be activated with the appropriate notification:
    - The alternate supplier from a multi-award agreement assumes the supply, on approval of contract holder/buyer, for the period of the shortage or as otherwise agreed
    - Contracted secondary supplier assumes the supply for the period of the shortage or as otherwise agreed and the primary supplier is accountable for any defined penalties
  - The contracted supplier arranges for an alternate pre-approved supplier to assume the supply for the period of the shortage or as otherwise agreed, and the primary supplier is accountable for any defined penalties
  - The contract holder/buyer may procure an acceptable substitute from an un-contracted supplier if the above options are not available
  - The contracting authority may need to compound a suitable alternate product using:
    - a commercially available product
    - a raw material
  - The contract holder/buyer may need to procure a different drug

2.6 Consequences of Failure To Meet Supply, Quality Assurance or Other Obligations

See Appendix A; Section 6

The financial consequences of a failure to supply or provide the required notifications, to meet quality obligations or which result from other breaches by the supplier of the terms of the supply agreement need to be clearly established within the contract. If a contracted supplier fails to supply, they must report demand information and replenishment timelines, so that others can intercede as fully as they are able, to meet patient demands. The extent to which the supplier is financially responsible for costs and other damages incurred by the customer, including the costs to source alternate products and other costs or expenses as a result of such events is a matter for negotiation between the customer and the supplier. There needs to be recognition and balance between the needs of the customer who bears considerable costs due to the failure to supply under the contract, and the competitive environment that continues to attract the supplier to invest in the product.

3 Recommendations for Adoption of Best Practices

The conditions, vulnerabilities, remedies and best practices identified in this guidance document represent a roadmap for continued improvement in contracting and procurement strategies to prevent, mitigate, and manage drug shortages.

The best practices and remedies discussed here acknowledge the realities of today's marketplace and offer protection for Canadian patients. Supply chain stakeholders can use this information to identify and guide required changes in practice, to communicate needs and expectations, and to collaborate on implementation of new approaches. It is understood that changes will have both anticipated and unforeseen consequences, therefore collaboration and ongoing communication will be essential. This guidance document needs to be widely shared with stakeholders so it can be used to identify, agree and act on opportunities for change.

Contracting and procurement cannot address all vulnerabilities in the Canadian drug supply chain. The MSSC can provide important leadership to address the broader supply chain vulnerabilities and remedies.

APPENDIX A – Example Supply Contract Practices to Reduce Drug Shortage Risk

Background:

This document provides core concepts and best practices for effective procurement of drug products, primarily focused on those aspects aimed at reducing the patient risks and significant cost and operational impact caused by drug supply shortages and recommendations with respect to corresponding language for inclusion in drug supply contracts. In developing these core concepts and best practices, common ground has been identified between all relevant stakeholders to enable improvements to the robustness and reliability of the drug supply chain in Canada.

It is recognized that there will be issues unique to a particular drug or situation that may require additional consideration, negotiation or terms in employing the best practices. A number of the concepts listed below may overlap and may be consolidated when drafting sample contract language.

1. Preliminary Quality Review and Performance Incentives

The primary purpose of the concepts/best practices under this heading is to structure the competitive selection process for drug supply in a manner that drives innovation and produces high-quality results, in terms of both the quality of supplier and the quality of product. The competitive selection process may include some or all of the following concepts:

1.1. Perform quality-based selective contracting, including due diligence research on the supplier and, as appropriate, the sub-suppliers and sub-contract holders, including review of:
- 1.1.1. quality procedures and compliance history under previous contracts;
- 1.1.2. financial stability if commercially available;
- 1.1.3. supplier's published sustainability and performance targets, including post-reporting as against those targets. Consider inclusion of those targets in the supply contract, as appropriate;
- 1.1.4. contingency plans to ensure security of supply and disaster response planning.

1.2. Consider the use of "pay for performance" payment differentials based on the supplier's compliance history with respect to quality and supply matters and targets.

1.3. Review public domain information on comparative supplier performance.

1.4. Consult with customer clinician/pharmacy personnel regarding risks and contingency planning for single sourced critical drugs.

2. Commitment to Supply

The primary purpose of the best practices discussed under this heading is to ensure that the customer (i.e. contract holder/buyer) receives appropriate assurances from the supplier that the supplier will supply the contracted drugs for the entire duration of the term of the supply contract. That is important because the customers will be relying on the promise of the supplier to ensure that the customer has access to adequate inventory to meet the needs of its patients. Where the supplier is unable to meet any of the following obligations, those exceptions should be clearly identified to the customer in advance of entering into the supply contract as that information will be important to allow the customer to take steps to plan for and mitigate against that risk.

2.1. The supply contract should contain a commitment by the manufacturer or importer (the "supplier") to supply the health care customer (the "customer") with the listed products (also referred to as "drugs" or "products") through the term of the supply contract (consequences of a shortage or recall dealt with below), including all:
- 2.1.1. specified formats ;
- 2.1.2. specified dosage;
- 2.1.3. specified packaging;

of the listed products.

2.2. The supply contract should require that the supplier be committed to do all they can to avoid a drug shortage. A drug shortage is defined as:
   2.2.1. Product discontinuation - Supplier stops producing product specified in the supply contract; or
   2.2.2. Product shortage - failure to supply products for a specified period of time; or
   2.2.3. Drug shortage inability to supply the product; to meet demand; or
   2.2.4. Restricted supply - unable to supply at least [110%] (specific level to be determined in negotiations with supplier) of demand for the product (without accounting for any substitutions) based on order history or historical consumption over the prior period (a year being most common).

2.3. No substitutions will occur without prior written approval of the customer (if substitutions are required due to shortage or recall substitutions will be dealt with under those provisions).

2.4. The supply contract should require the supplier to provide notification to the customer and on www.drugshortagescanada.ca of its decision to voluntarily stop production of a drug or drug format or of an actual or potential drug shortage. In all cases, notice should be provided as soon as possible when supplier becomes aware and/or no less than a minimum time period in advance of production stoppage. That time period could be as little as [six] months but may be longer depending on the impact that a decision to discontinue supply would have on the customer or its patients. That time period would be assessed and negotiated in each supply contract and updated to reflect mandatory drug shortage reporting obligations.

2.5. The supply contract should include a predefined delivery schedule for each product from the date that the supplier receives an order from the customer (based on schedule of delivery times by product/product categories). If the predefined delivery schedule is not met, the customer has the right to cancel the order and purchase the particular product(s) from an alternate supplier.

2.6. The supply contract should contain an obligation by the supplier to notify the customer of new product offerings and the opportunity to include those new products in the supply contract;

2.7. The supply contract should contain a requirement that all product supplied has, at the time it is delivered to the customer, a minimum remaining shelf-life. The amount of the shelf-life will vary by product.

2.8. In order to obtain reasonable assurances from the supplier of the supplier's commitment to supply and to take the steps noted below to reasonably ensure security of supply, the supply contract should not require customers to purchase minimum volumes over the life of the contract.

2.9. The supply contract should require the supplier to provide each customer/contracting authority with quarterly reports of all products purchased by the customer and the inventory in days on hand available throughout the supplier's supply chain, which includes the supplier's direct supply partners and the supplier's distributors, in order to allow the customer to monitor the supply under that contract and monitor its dependence on a particular supplier.

3. Security of Supply - General

The primary purpose of the best practices discussed under this heading is to encourage good supply chain and operations management practices be adopted by the supplier (and are capable of being reviewed and monitored by the customer) in order to minimize the likelihood of a shortage occurring and to ensure that, where supply chain risk does exist, the customer is informed and has the opportunity to plan accordingly.

The supply contract should include:

3.1. Up-front and [semi-]annual reports be provided to the customer/contract holder by the supplier confirming:

3.1.1. the safety stock maintained by the supplier for agreed products;
3.1.2. the supplier's capacity and any excess capacity over its existing customer's forecasted demands; and,
3.1.3. which products the supplier has identified are single sourced at any step of the supply chain (including, raw materials, API, manufacturing, packaging/fill and finish) and the supplier attests the mitigation strategies being employed where possible by the supplier to reduce the risk associated with any single sourced items and are available on request;

3.2. The supplier is required to maintain an appropriate level of safety stock based upon ongoing consumption and shelf-life. Minimum safety stock will be agreed upon for all key products.

3.3. The supplier commits to make available a minimum volume capacity (on a product-by-product basis) to the customer (or customer group) for key products to be identified in the supply contract.

3.4. The Supplier guarantees its turn-up ratio (the amount above the normal consumption that it can supply with little or no notice and which will not require the use of safety stock). In addition, the supplier will indicate the rate at which production can be increased over specified time periods such as 60 and 120 days.

3.5. The supplier commitment to consultation with the customer for implementation timelines prior to the supplier implementing a change which would limit or remove availability of any particular formulation or dosage of a listed product. In all cases, notice should be provided as soon as supplier is aware and/or no less than a minimum of 6 (six) months in advance of changes to the product.

3.6. Where there is an industry wide shortage of products, the supplier will give priority to orders from customers and will establish an equitable allocation process for the product for the duration of that emergency or shortage.

3.7. Suppliers will be required to demonstrate, through life of the supply contract, that they have up-to-date and tested security of supply and business continuity plans (including the supplier's process to allocated drugs during a shortage) (see 3.6 above) and that these plans have been developed using standard protocols such as Failure Effect Mode Analysis. In addition, supplier will demonstrate that these plans:
3.7.1. Are tested annually; and,
3.7.2. Provide:
3.7.2.1. protection against adverse business disruptions;
3.7.2.2. identification of any single source materials or processes; and
3.7.2.3. identification of contingency plans to address failure in single source materials or manufacturing processes which would interrupt supply if they fail or performance is degraded.

3.8. Copies of reports demonstrating the matters in s. 3.7 will be provided by the Supplier to the customer annually and within 30 days after the completion of the report. Where the report indicates that corrective action is required, the supplier will indicate the corrective action within specified time frames and provide to the customer regular status reports at intervals which are commensurate with the timeline for corrective action.

3.9. Supplier will provide to the customer material changes in its capability to supply the product related to production planning, inventory and logistics processes for critical drugs and/or sole source drugs.

3.10. Supplier will provide quarterly reports on inventory levels held throughout its supply chain by location. Report will indicate the supply level in terms of days on hand against a normal as well as maximum demand as determined by turn-up ratio.

3.11. In addition, the supplier will maintain a dedicated amount of stock for each customer under a supply contract for a specified quantity of product and time period. As a potential alternate risk mitigation strategy, the supply contract may provide that the supplier create a partnership with a

centralized distributor to ensure separation of the supplier's product inventory so that the supplier's entire inventory of a particular product is not stored at one location. Provided that inventory is available for distribution to the customer under the supply contract, any inventory held by the supplier's authorized distributor would be included in determining whether the supplier has met its minimum safety stock commitments (see 3.2) in the supply contract. This risk mitigation could also be achieved by the manufacturer having multiple warehouses in different geographic regions for the storage of inventory/safety stock.

4. Quality Assurance

The primary purpose of the concepts/best practices discussed under this heading is to require that certain quality control processes be in place and to ensure that the supplier is communicating the status of its quality processes advising the customer in a timely manner of any regulatory actions or quality assurance events that have a reasonable potential to lead to a supply disruption. It is acknowledged that many of the events noted below may not ultimately lead to a supply disruption. However, the goal is to ensure that the customer is not surprised and has the opportunity to enhance its contingency planning efforts in light of new information.

The supply contract should include the following:

4.1. That the supplier warrants that all products and facilities used to manufacture the products are in compliance with all applicable laws, regulations, etc. and that products meet all approved and all published specifications, are not adulterated or misbranded and do not infringe third party intellectual property rights. Standard indemnification terms to be provided to customer.

4.2. Suppliers will be held accountable to provide timely advance notification of anticipated or emerging drug shortages:

4.2.1. Supplier will be required to track and report when inventory levels (national & local) drop below pre-determined levels;

4.2.2. Remediation plans will need to be activated once inventory levels drop below a specific level;

4.2.3. Protocols for notification of a shortage event and the initiation of contingency plans need to be defined and tested; and,

4.2.4. Suppliers must comply with the regulatory requirements to report all anticipated and actual shortages and discontinuance on www.drugshortagescanada.ca. no less than six months in advance or if known less than six months in advance, it should be reported within five days from when they become aware of the shortage and/or discontinuation .

4.3. Suppliers will provide customers with prompt notice of any regulatory action or [non-routine] inspection by any regulatory authority with respect to any product or any manufacturing site at which the products are being manufactured that may result in a drug shortage or supply disruption.

4.4. If any regulatory body issued a notice that may result in a drug shortage or supply disruption with respect to any product or manufacturing site at which a product is manufactured, supplier will provide notification to the customer within [72 hours] of receipt. This will include notification regarding:

- Health Canada inspection reports or regulatory letters either in relation to their regulatory activities or drug products
- When the manufacturing establishment or any related establishment performing activities regulated under the Food and Drugs Act (i.e. fabricate, package/label, test, distribute, import and wholesale) has had its Establishment License suspended or cancelled, or Terms and Conditions have been placed on it.

- FDA warning letters, FDA Form 483s or equivalent observation letters from other regulatory bodies outside Canada

4.5. The supplier will be responsible to ensure its suppliers and subcontract holders comply with the performance, quality assurance and other obligations of the supply agreement.

4.6. The supply contract may address a customer's right of inspection and audit as appropriate under specified conditions as negotiated between the two parties.

5. Shortages and Recalls

The primary purpose of the concepts/best practices discussed under this heading is to ensure that there is a common understanding and agreement between the supplier and the customer as to how the supplier will manage a shortage of one or more of the drugs covered under the supply contract. To do so, the supply contract should address the following:

5.1. Suppliers will have an obligation to ensure continuity of supply and collaborate to identify substitutes (alternatives by formulation, method of administration and dosage/size as is identified following ISMP Canada standards, policies and principles around the safe medication practices), for all treatment modalities, which if the supply of the primary drug is disrupted will be provided by the supplier:

5.1.1. Supplier's substitute drugs and format/formulation will require pre-approval by the customer;

5.1.2. Supplier substitute drugs will be reviewed by the supplier with the customer on a regular basis to ensure that they are aligned with current practice as well as format and formulation availability;

5.1.3. The supplier will identify therapeutic alternatives on the relevant shortage posting on www.drugshortagescanada.ca; and,

5.1.4. If supplier is unable to provide an approved substitute drug then the supplier will cover the full cost of the customer identifying, finding and acquiring substitutes and format that is reasonably accepted to be a substitute.

5.2. Supplier will provide its written policies on shortage and recall management and documentation on their recall process (internal & externally initiated) and shall notify the customer immediately and in writing if any recall policies are activated at the source of manufacturing or in other organizations within the supply chain that may potentially affect the provision of the contracted product. Supplier will provide annual evidence that the recall processes and policies have been reviewed and that the supplier and its supply chain partners have the capability to manage a shortage or recall in a timely manner.

5.3. Supply contract will provide advance notice as soon as they are aware, of the allocation process and protocols to be used to allocate existing inventory between customers if a shortage/recall occurs. Allocation protocols will cover all the specified product and product format identified in the contract.

5.4. Supplier to provide regular updates (weekly or more frequent if requested by customer) with respect to any shortage or recall and provide customer with copies of all communications with regulatory authorities with respect to the recall.

5.5. Supplier to:

5.5.1. comply with all applicable laws and regulations applicable to any shortage or recall and with the Protocol for the Notification and Communication of Drug Shortages; and,

5.5.2. provide public notification no less than six months in advance or if known less than six months in advance, it should be reported within five days from when they become aware of it on www.drugshortagescanada.ca.

6. Consequences of Failure to Meet Supply, Quality Assurance or Other Obligations

The best practices set out above do not address the financial consequences of a failure to supply or provide the required notifications, to meet quality obligations or which result from other breaches by the

supplier of the terms of the supply agreement. The extent to which the supplier is financially responsible for costs and other damages incurred by the customer, including the costs to source alternate products and other costs or expenses as a result of such events is a matter for negotiation between the customer and the supplier.

7. Other Corresponding Terms

The primary purpose of the concepts/best practices discussed under this heading is to address how certain other terms in a supply contract should be considered and adjusted to align with the drug shortage mitigation concepts noted above. The supply contract should include terms to address the following:

7.1. Standard term and termination provisions and not permit or, as a minimum, should supercede termination for convenience by the supplier. If the supplier has the right to terminate for convenience, the customer has no security of supply. Where the supplier has a right to terminate without reason, the supplier must provide a minimum amount of notice. The amount of the notice period will depend on the customer's overall reliance on the group of products being supplied by the supplier and should be no less than the notice period referred to in s. 1.4 above.

7.2. On termination, unless otherwise directed by the customer, supplier will continue to fill orders placed prior to or within xxx days of termination, as agreed to between supplier and contract holder/buyer

7.3. Standard term and term provisions should include a minimum amount of notice when the contract holder/buyer informs the supplier of termination. Regardless of rationale or reason (e.g. formulary committee or provincial drug program to delist a molecule/drug), there should be a fair and equitable washout period for on-hand stock in the supply chain to be depleted. Alternately, if adequate notice is not possible, then compensation for the on-hand stock or handling of on-hand stock should be negotiated between the contract holder/buyer and supplier.

7.4. Force majeure rights should be limited and not include disruptions that could have been mitigated through security of supply planning (e.g. by having dual manufacturing sites, and multiple sources of raw materials, API, etc. where possible).

7.5. Rights of assignment, including appropriate limitations on the supplier's right to assign, should be specifically considered and addressed based on the circumstances and with a view to ensuring consistency of quality and security of supply.

APPENDIX B – Summary Chart

Condition	Vulnerabilities	Contracting Practices	Appendix A Example
Globalization: • Most manufacturers of drugs in Canada are global and decisions made on global basis • Manufacturing sites must meet foreign regulatory standards	• Canadian small global share (2-3%) and low priority and long supply chain • Global manufacturing increasingly dependent on single supply and more vulnerable to adverse events • Growth of product lines without increased capacity • Decisions are business based at global level, not at local Canadian level	The contract, to the extent possible, will reflect provisions wherein the supplier has committed to take reasonably necessary management and operational practices based on their resources from their global supply chain to reduce the likelihood of a shortage which may include: • a notification plan for adverse events in the global supply process which would potentially disrupt Canadian supply • a well-managed plan for appropriate safety stock within the global and local supply chain; including protected inventory • contingency plans for diversity in global supply (i.e. for manufacturing components, including API source, or for capacity, or other options)	2. Commitment to Supply 3. Security of Supply - General

Complexity and Responsiveness: Most of the manufacturer systems are complex and time sensitive and not reactive to short term changes
• Product development
• Sterile manufacturing facility construction and maintenance
• Production planning
• Regulatory processes and procedures
	• Supply chain has long timeline for response
	• The whole system is adversely affected by:
	  • unforeseen disruption problems
	  • reductions in capacity for various reasons
	  • problems from sole source component supply
	• Supplier response to other market shortages may not be good business decision due to long reaction time
		The contract, to the extent possible, will reflect provisions to which the contractor and supplier have agreed wherein:
		• the supplier will:
		  • establish contingency plans for high risk production processes, single source components, and business partner's supply chain
		  • establish notification and communication time scales appropriate for supplier remediation plans
		  • provide prompt notification of early warning events that may reasonably result in a shortage (regulatory warning, single source component problem, planned reduction in production or capacity)
		  • provide clear
			2. Commitment to Supply
			3. Security of Supply – General
			4. Quality Assurance

Condition	Vulnerabilities	Contracting Practices	Appendix A Example
		communications as to how any shortages will be managed • the contractor and supplier have a clear understanding of any penalties that will accrue as a result of an undersupply of drug	
Distribution and Inventories: Supply management practices have not evolved to adapt to drug shortages	• Many stakeholders in many countries involved in global supply chain • Historic safety stock levels have not been adapted to current state of planned reductions in capacity or unplanned increases in demand (i.e. re-locating inventory, implementing allocation program) • Low inventories in supply chain due to Just-in-Time inventory practices to maximize local efficiencies • Lack of reliable information, coordination and communication make response to shortages difficult to manage	The contract, to the extent possible, will reflect provisions to which the contractor and supplier have agreed wherein: • there is appropriate safety inventory for all stakeholders • inventory management agreements are established with distributors or suppliers should a shortage be anticipated, • there is a commitment from the supplier to disclose essential local supply chain information and establish notification and communications protocols • that existing inventory is managed through an allocation plan	5. Shortages and Recalls
Quality and Price • Price pressure positively affects public health care providers but negatively affects competition • Quality of supply is not rewarded	• Suppliers may exit the market if downward price pressures and upward quality cost pressures do not yield a fair return • Product scarcity and shortages have significant patient and financial impact	The contractor's approach to the competitive market, to the extent possible, will reflect the outcome the contractor wants to achieve in the balance between patient safety, occupational health and safety of healthcare providers, quality of supply, and price. • Suppliers, in their response to a request for a competitive proposal, are transparent about their practices that indicate quality of their supply	1. Preliminary Quality Review and Performance Incentives 2. Commitment to supply

Condition	Vulnerabilities	Contracting Practices	Appendix A Example
		• Contractor will include incentives for quality of supply	
Procurement Practices Contracting practices have not evolved to adapt to changes in production and supply of drugs	• Single award practices when multiple suppliers exist • Competitive practices where price is more important than supplier historical quality of supply • Contract cycles create barriers to new market entries • Resistance to change by all stakeholders	The contractor's approach to the competitive market, to the extent possible, will reflect: • Stratification of goods for different contracting strategies • the importance of supplier performance that includes quality of supply • a risk designation of the products • strategies that encourage diversity (multi-supplier awards) • strategies that encourage new market entries • best practices to mitigate drug shortages through contracting and procurement	3. Preliminary Quality Review and Performance Incentives 4. Commitment to supply

APPENDIX C – Broader Supply Chain Remedies

Appendix C summarizes additional supply chain remedies outside of contracting and procurement processes. Key areas for further action include:

- Ongoing analysis of drug shortage root causes and strategies to address them
- Industry stakeholder agreement on best practices for allocation plans that will meet the needs of patients and stakeholders
- Mechanisms to ensure guaranteed and secured inventory under contract along with national action on protocols that will support patient access to medically necessary drugs using principles of fair share
- Continued enhancements to www.drugshortagescanada.ca to make it the prime resource consolidating information from all suppliers. This will include status of shortages as well as other key regulatory and industry information that might provide early warnings for potential disruptions in the supply chain as well as comprehensive information to help manage shortages
- Continued enhancements will include future implementation of mandatory drug shortage reporting

Many of the supply chain vulnerabilities listed in this guidance document can be mitigated through collaboration and action beyond contracting and procurement. This list summarizes actions from Section 1 that require further consideration.

- Improve access to knowledge of viable global sourcing options in the event of a shortage in Canada of a critical drug
- To ensure security of supply each end user (consuming organization) will require segregation of safety stock to support their needs. This will impact the efficiency and cost of procurement
- Contract holders collaborate on national identification of critical, high priority products for which a higher specified level of performance is required
- Commit to increased inventory holding throughout the supply chain at manufacturer, distributor and retail and institutional pharmacy sites
- Improve standardized allocation process through normal distribution channel
- Impose limitations on purchases and alerts for unusual purchasing activity
- Improve national sales data to support better forecasted inventory holdings
- Implement a process for health care providers to notify suppliers and distributors of alternate therapy plans during a shortage or changes to normal practice which would affect inventory needs
- Industry stakeholders adopt national standards for tracking and tracing inventory

APPENDIX D – Contract and Procurement Best Practice Working Group Members

NAME	ORGANIZATION
Kathy Boyle (Chair)	Health*PRO* Procurement Services Inc.
Aidan Griffin (Vulnerabilities Lead)	Pfizer Canada
Doug Kent (Contracting Best Practices Lead)	Health Shared Services BC
Carmen Bell	University of Saskatchewan
Dawn Jennings	Health*PRO* Procurement Services Inc.
Janet Grove	Health Shared Services BC
Jaimie Boyd	Health Canada
Janis Johnson	Saskatchewan Ministry of Health
Jennifer Potvin	Health*PRO* Procurement Services Inc.
Julie Tam	Canadian Generic Pharmaceutical Association
Justin Bates	Neighbourhood Pharmacy Association of Canada
Keith McIntosh	Innovative Medicines Canada (Formerly known as Rx&D, Canada's Research-Based Pharmaceutical Companies)
Michelle Grant	Health Shared Services BC
Mike Blanchard	Medbuy Corporation
Patricia Macgregor	The Hospital for Sick Children
Rob McCord	Neighbourhood Pharmacy Association of Canada
Stuart Forestell	Health Canada
Sylvie Boudreau	SigmaSanté
Sylvie VanderCruyssen	Health Shared Services BC
Terri Power	Canadian Association for Pharmacy Distribution
Thomas Gray	Capital Health, Provincial Drug Distribution Program

Facilitation and report preparation by Carolynne Fletcher Wintrip, Luminus Learning Inc.