Consultation on improving access to drugs and other health products in Canada

Contents

Dear Drug Shortages Task Force,

On behalf of Medtech Canada and our member organizations, thank you for the opportunity to provide industry perspectives on the Consultation on improving access to drugs and other health products in Canada.

Medtech Canada is the national association representing Canada's innovative medical technology (medtech) industry. Representing approximately 180 medtech companies, support services and associations (ranging from Canadian-owned to multinationals) and having partnerships with national and international related associations such as AdvaMed, DITTA and the Inter-American coalition for regulatory convergence (Medical Device Sector), Medtech Canada works closely with government and healthcare stakeholders to deliver a patient-centered, safe, accessible, innovative and sustainable universal healthcare system supported by the use of medical technology.

Medtech Canada has been engaged with various multi-stakeholder committees and consultations in the past year such as the Medical Devices Shortages Multi-Stakeholder Committee, Pandemic Planning and Health Products Supply Chain Advisory Committee. We have gathered various observations throughout this multi-faceted participation and have been regularly providing them to the applicable committees. We are also happy to collate them and provide them within this consultation.

Medtech Canada General Recommendations:

1. Establish a process to define and manage priority issues and signals
   We need to have the ability to accurately identify signals as well as prioritize issues consistently and methodically. It is important to identify what elements are impacting our supply chain during regular cadence of business and during specific surges and then address those that are identified as a top priority.

2. Centralized database
   Create a centralized database that receives feedback (supply chain signals and actual shortages) from ALL aspects of the supply chain. This would include, but is not limited to, suppliers, logistics and transportation, labour unions, and healthcare providers. This recommended centralized database should be managed by an independent agency and should ensure industry and healthcare providers (such as clinicians, physicians, nurses, industry, biomedical engineers, supply chain experts, transportation representatives, and other appropriate professionals) are engaged to provide specific input into the database. This independent agency would then subsequently (with the help of identified Subject Matter Experts and related committees) identify national shortages and assist industry and healthcare to engage all related government agencies (federal and provincial) to facilitate resolution.

3. Holistic national and international regulatory agility
   Identify and work with all national (federal and provincial) as well as international regulatory agencies who impact the medtech industry (e.g., but not limited to, electrical approval, Quebec

language requirements, PMRA, plastics, PFAS, environmental as well as new and evolving regulations such as Bill C-27) to simplify and align the current complex regulatory pathways.

Establish and adopt international approvals / recognition within the medtech industry such as Mutual Recognition Agreements (Mutual recognition agreements (MRA) | European Medicines Agency (europa.eu) which is currently seen with drugs.

The medtech industry is currently experiencing supply challenges, which are exacerbated by the increasingly complex regulatory pathways (which become even more challenging in times of shortages). Currently multiple approvals are required (each with their own unique pathways and timelines) to bring alternate medical devices into Canada during a shortage.

4. Implement a "Regulatory Change Control" process within the government's Shortages unit.
Currently, there is fragmentation in the system where government agency changes to regulations and policies are not necessarily aligned.

   Once a process is identified, mapped and implemented around navigating today's complex national and international regulatory framework to facilitate alternate products in times of a shortage, this process will need to remain current and updated. To ensure the process remains current and effective, it is recommended that a Regulatory Change Control process be implemented within the government group who manages shortages. This would include collaborating with existing and new agencies to align on activities that can take place in case of shortages and may result in special regulatory updates within the various acts as was done for COVID-19 within the Medical Device Regulations. Clarity of process and governance could ease confusion and prevent unplanned inventory challenges as well as quicker resolution of shortages.

5. Parallel single review portal
   Medtech Canada recommends that a single portal be developed where industry can apply for an exceptional importation in parallel to all federal and provincial regulatory agencies that affect the applicable medical device. For example, in the case of a ventilator, the potential agencies would be Health Canada MDD, electrical approval agencies of the provinces and territories, as well as the Office Québécois de la langue française in Quebec. All applicable agencies would review the application in parallel with a specific timeline aligned with the urgency of the shortage and ideally provide their response simultaneously. A perfect example that can be used is the current eSTAR project (Health Canada and FDA eSTAR pilot: Notice to industry - Canada.ca). This project is being coordinated by Health Canada and the US FDA where a manufacturer can apply through single portal to both Health Canada and the USA FDA.

   It's important to note that this process will provide further regulatory agility, as in some cases a non-unanimous approval may still mean that the device can be imported and sold but may limit distribution to specific provinces providing at least partial relief as well as transparency and speed.

6. Common definitions
   The word “shortages” is being used to define various situations which may or may not be an actual shortage. Additionally, the presumption that a shortage is always critical and/or that it is caused by industry is also leading to potential resolutions not aligned with the actual issue.

   It's important that formal definitions be created so that industry, healthcare and regulatory agencies can communicate effectively on these issues. Appendix #2 – Definitions represents the initial recommendations that were submitted to the Medical Devices Shortages Multi-Stakeholder Committee Secretariat to assist in developing these definitions. Subsequently, we have met and continued with developing these definitions.

7. Health Canada empowerment during a critical national shortage
   As indicated in above recommendations #3,4 and 5, our national and international regulatory framework is extremely complex. In times of urgent need, there may be situations where MDD may need to make a final decision on a specific device in order to treat a critical shortage. In this situation, we recommend that Health Canada (Medical Devices Directorate in the case of the Medtech Canada ecosystem) is empowered to make final decisions on behalf of federal and provincial bodies to approve medical devices for importation due to shortages (exceptional importation).

Detailed review of consultation document and related feedback

1. Landscape

This section, within the consultation document, indicated that the root cause of shortages is when the manufacturer is unable to meet the demand. Later, in the Causes section, it addresses a few additional causes, however the focal point still appears to be the manufacturer as the key source of issues; this is an oversimplification. Shortages occur due to various external factors such as:

- Geopolitical issues and trade disagreements
- Environmental disasters
- Transportation issues, including a lack of specific transportation for temperature-sensitive products or products that cannot be air-shipped due to their TDG classification.
- Labour issues
- Lack of communication and insufficient demand management by healthcare facilities for normal and spike usage
- Regulatory changes both within and outside Canada affecting the ability to import and/or manufacture for the Canadian healthcare ecosystem
- Duplicate and/or contradictory regulatory requirements and oversight at the federal and provincial level that slow down or stop a company from importing a medical device (to support normal business or shortage substitution)
- Raw material shortages

- Lack of qualified labour due to increased cost of living / brain drain (to USA and other countries) etc.
- Lack of detailed and comprehensive demand planning to help industry and health care providers prepare adequate inventory for unusual procedural volume.
- Pandemic stockpiling which can create artificial shortages (similar to the toilet paper shortage during the COVID-19 pandemic)

It is important to note that the above challenges can be encountered both within and outside of Canada. As a first step of planning to resolve shortages we need to acknowledge the varying causes of shortages. Focusing only on the manufacturer shortages will not help us resolve the shortages we are seeing in our Canadian ecosystem and may cause an adverse effect of industry choosing to exit a Canadian market that is not collaborative.

2. Current toolbox

This section speaks to the current mechanisms that exist to mitigate shortages. Although we recognize that the drug shortages process and database has been in place for quite some time and that both the Medical Devices Shortages Multi-Stakeholder Committee Secretariat, as well as the Health Products Supply Chain Advisory Committee are working collaboratively to improve our joint ability to identify and resolve (or mitigate) shortages quickly, we believe that the below feedback on current initiatives that have taken place, in addition to the recommendations noted above, would assist in further improving the current efforts:

2.1 Require manufacturers of prescription drugs and certain medical devices to report shortages

In order to have a full picture of the issue, data must be collected from all, not only one, of the sources. This links to the above section (Landscape) where there is a dangerous misconception that all shortages are manufacturer driven.

Current requirements apply only to certain regulated members such as manufacturers and importers / distributors; the medical device ecosystem is much broader and shortage reporting should be equally mandated from all members of the supply chain such as hospitals, physicians, LTC facilities as well as third party service providers. Requiring only one portion of the supply chain to report may create a delay in the signal detection of a shortage. It may also perpetuate inaccurate signals e.g., a manufacturer may state there is a shortage while there may be a decrease in demand for that product.

In summary, as noted above as well as in our initial list of recommendations (Recommendation #1 and Recommendation #2), the central database for drugs as well as the one in development for medical devices must capture signals from all aspects of the supply chain to provide a realistic and real-time database from which decisions can be made. Mandatory reporting should be from all stakeholders to prevent the signals misfiring and misplaced effort.

2.2 Prohibit the export of drugs made for the Canadian market when it can cause or worsen a shortage.

This prohibition is of concern to us, as Canada is trying to attract both pharma and medtech companies to move manufacturing here (as part of the efforts to reduce shortages and improve reduction of identified shortages).

By creating this potential prohibition, which would challenge a company's ability to meet its contractual obligations, it will deter companies from considering Canada as a manufacturing location and will have a negative impact on the government's Made-in-Canada initiative.

Medtech Canada recommends an alternate, positive, and collaborative joint venture such as creating Canadian reservoirs of raw materials and/or components that can be provided to a larger scope of manufacturers in cases of shortages, with the caveat that these materials only be used to produce products (medical devices or drugs) for the Canadian market. This would assist in diverting the products into the Canadian market without impacting contractual obligations and will also assist in the financial challenges companies face during a spike in demand. The centralized database as well as the ability to prioritize and identify early signals (Recommendation #1 and Recommendation #2) would be a key element in identifying the appropriate raw materials and/or components that would be part of the reservoir.

An example would be specific materials such as Tyvek which is used in various medical devices and drugs requiring a sterile format and where an early signal of a Tyvek raw material shortage may require that this material be added to the national reservoir.

2.3 Work with supply chain actors to ramp up domestic production or source another supply.

The Canadian supply chain needs to consider all the key players within the healthcare supply chain. One of these critical key players is the transportation industry. Canada's geography and population distribution is challenging to support even during normal operation. These challenges are not only related to the distance between the communities, but also to the mode of transportation (air / water / ground / heated / cold chain / TDG etc.) that healthcare products require to reach the communities while maintaining their efficacy, performance, and safety.

Consideration needs to be given to the ever-evolving landscape of healthcare products to ensure that the specialized transportation to deliver products is aligned with the evolution of healthcare. For example, in drugs, one vaccine may require cold chain distribution and an alternate supplier may not. This allows only one of them to have a larger reach into remote communities. An increase in "cold chain" requirement is also seen in the area of medical devices, especially due to the increase technology and sensitive electronics which require heat protection. This needs to be incorporated in any future shortages planning as lack of proper transportation can also cause a shortage.

2.4 Authorize the importation of products that are not authorized for sale in Canada but are manufactured to similar standards.

While we support this effort in times of shortages, it has come to our attention that the exceptional importation authorization granted was only from one regulatory agency (Health Canada) and did not represent an authorization from the various other federal and/or provincial bodies that regulate the products therefore the authorization would not result in the product being approved for importation into Canada.

Medical devices are regulated by various federal and provincial regulations. These jurisdictions would be required to provide individual unique authorization (such as the one provided by Health Canada) in order for the manufacturer and/or importer to import the device quickly in time of a shortage. This may not be feasible for the manufacturer/ importer, nor would the timelines for a multiple jurisdictional review amount to a speedy approval to import.

An example of the various and complex regulatory frameworks could be ventilators, a publicly known shortage during the COVID-19 pandemic. In the case of supply shortage, these ventilators would potentially require exceptional importation approval not only from Health Canada, but also from:

- Electrical standards
- Quebec language requirements
- PMRA (if applicable for some Class 1 accessories)
- Any other applicable federal and provincial regulatory oversight entities as applicable at the time of the shortage (for example, potential new plastics labelling requirements, PFAS etc.)

There is a two-pronged approach recommended in this complex regulatory framework. Medtech Canada has identified the two approaches in our initial recommendations; Recommendation #3 and Recommendation #5.

Recommendation #3 speaks to a holistic national and international regulatory agility to simplify the regulatory landscape for healthcare products, however also recognizes that after this simplification, there may still be parallel bodies where approvals (for exceptional importation) may be required, which is where Recommendation #5 would apply, by creating a parallel single review portal for shortages and enabling all applicable jurisdictions to review and approve jointly, and in parallel, any exceptional importation requests.

Medtech Canada further recommends that Health Canada be empowered during a critical national shortage (see Recommendation #7). This would assign a key decision maker during a critical national shortage of a healthcare product with "Minister Veto Power". Health Canada (Medical Devices Directorate in our case) would be empowered to make final decisions (regarding exceptional importation) on behalf of all federal and provincial bodies in order to ensure that medical devices reach the patient without having to go through the aggregate burden that exists today, and which would result in critical impact to our patients.

2.5 Procure and stockpile products for a limited time (as we did with the COVID-19 Critical Drug Reserve)

It is important to note that in the last paragraph of the section "Current toolbox", it is made clear that "stockpiling" of finished medical devices would not be a solution. It states: "*The COVID-19 pandemic highlighted vulnerabilities in the supply chain. The effects of the pandemic are now less severe, but the number of critical drug shortages is as high as it was at the height of the pandemic. The difference is that these shortages are no longer related to products used to treat patients with COVID-19*."

Stockpiling may be an appropriate strategy for drugs as there are some vital products such as antibiotics, analgesics, etc. that are used in most healthcare crises. However, with respect to medical devices, predicting what products would be needed for a specific shortage (and, therefore, stockpiling them) would be extremely challenging and, potentially, cost prohibitive.

With a variety of situations (such as pandemic, endemic, geopolitical, strikes, environmental) potentially causing shortages, stockpiling the correct devices does not appear to be a realistic expectation.

Previously within this document we have identified some solutions that would assist in narrowing down, focusing and identifying the most affected products as well as alternate solutions to stockpiling finished medical devices.

1. Proper and early data collection, analysis, and signal detection
   This is discussed in our Recommendations #1 and Recommendation #2
2. Creation of Raw Material and Component Reservoirs
   In section 2.2 we discuss the alternate to finished goods stockpiling which would be the creation and procurement of raw materials and components for medical devices and drugs that could be used for local and or close-proximity manufacturing of finished healthcare products for the Canadian market.

   The rationale behind the recommendation for the creation of raw material and components reservoir is that these have more flexibility in where they can be utilized and what finished product can be made. In addition, the shelf life of the ultimate finished good manufactured from some of these raw materials may extend beyond what the equivalent reservoir of the same finished good medical device. This type of stockpiling would need to be coupled with the identification of local or proximal companies that can manufacture these finished products.

In addition, we would recommend considering the following options:

- Identifying within our current regulated industry which organizations manufacture specific products. Existing companies with authorized products in Canada could be the first line of defence in the event of a shortage.
- Identify which companies have previously had Canadian licences and engage them as the second line of defence in a shortage situation. It is reasonable to assume that they have quality systems in place and may be able to respond in an emergency.
- Identify companies that do not currently import into Canada and engage them about the devices they manufacture and their potential ability to supply Canada during an emergency.

- The above actions would need to be conducted in real-time and on an ongoing basis i.e., potentially every 12 months as the medtech industry is constantly evolving with the mergers, divestments, and consolidations of organizations and this database of products by company would need to be continuously updated and maintained.

3. Discussion questions and key areas for Action

Key area 1: Improved communication and transparency

A few key areas to consider when looking into improved communication and transparency are:

1. Disclosure and alignment on type and breadth of information shared

Better communications and information sharing is key to preventing and resolving shortages quickly. It is however important to also identify what information will help with shortage resolutions and where too much information (being requested) will be counterproductive, will create misinformation, panic and result in a self-fulfilling shortage.

We can see a perfect example that occurred during COVID-19 where misinformation caused shortages:

> As grocery stores and other retailers usually only keep several weeks' worth of toilet paper in their warehouses, the sudden increase in demand, largely fueled by panic-buying and hoarding, quickly depleted stocks while the supply chain struggled to react to the severe spike in demand.

2. Sources of information and what data is being collected and shared

With the volume of information that we may collect to avoid or mitigate shortages, the data being collected needs to be precise and purposeful. Sources of information must be reliable, and the data collected needs to be objective and reflective of the whole ecosystem.

Currently, the process of identifying a medical device signal as a true shortage is overseen by a committee that reviews the signals and decides on whether they are of national impact. The Medical Devices Shortages Multi-Stakeholder Committee Secretariat is comprised of Health Canada, provincial and territories representatives, purchasing organizations and Medtech Canada (representing industry). Medtech Canada recognizes the importance of this type of committee and recommends that clinicians as well as other key industry representatives (such as transportation) be added to the multistakeholder committee in order to help identify and address shortage concerns. Due to the variety of medical devices, there may be a need to subdivide the group into logical committees based on general device category to ensure that the discussion can be focused and with the right subject matter experts at the table.

As noted in the opening Recommendations earlier on in this document (Recommendation #1 and Recommendation #2), Medtech Canada has also shared and presented to the Medical Devices Shortages Multi-Stakeholder Committee a recommendation on data collection parameters (see Appendix #1) that would focus on salient details and assist in this information gathering. Of important note, this database is different from the one currently regulated by Health Canada (both drugs and devices) as it requires not only manufacturers (in the case of drugs) or importers/distributors (drugs and devices) but also healthcare providers to enter information into the database.

Regarding the platform to be used for this database, Medtech Canada recognizes the excellent work that the Drug Shortages Group has done over the past 10 years in implementing a validated system that support the Drug Shortages Database. To reduce time for a similar (yet more complex) implementation for medical devices, we recommend using the same platform and adapting it to the medical device needs.

3. Geography and extent of perceived shortage

Some perceived shortages are local and not national; without the proper channels of evaluation and communication, these local signals can result in unnecessary panic and in turn, spike purchasing. Dissemination to the consumer and to healthcare providers without a formal process may cause the opposite effect than intended.

Prescribed and controlled escalation must be in place to better plan and mitigate a shortage. Within healthcare, it is important to avoid subjectivity when discussing shortages and to plan the proper escalation mode. For example, is a pediatric shortage more critical than a regular shortage? Will the number of affected individuals impact the criticality? If so, what are the volumes that would define the different escalation and criticality of a shortage? We need to be able to prioritize and objectivity needs to be pre-defined and be implemented throughout the whole process.

In order to assist in the implementation of the above process, the following recommendations (found within this document) would be applicable:

- Recommendation #1 - Establish a process to define and manage priority issues and signals
- Recommendation #2 - Create a centralized database
- Recommendation #6 - Implement and maintain a database of common definitions to be used when discussing shortages

Questions for discussion:

What are your biggest challenges in getting key information to help you deal with shortages?

The largest challenge is that the information being shared is one-sided, not providing the full picture and resulting in poor root-cause analysis and corrective actions. The key information needs to be provided by the entire supply chain continuum and not just specific sources. As noted previously (See Recommendation #2 , Section 2.1 and Section 2.2) information needs to be received from healthcare providers as much as from the manufacturers, importers and distributors as well as third party medical

device service providers, transportation and all other members of the medtech ecosystem; they all play a role to support signal detection and shortage resolutions. In addition, Section 2.4 also identifies the need to also receive key information from the various Canadian national and provincial agencies that govern our medical devices. This advances resolution of shortages by providing industry with clear direction on process to get products into Canada in a timely fashion during a critical shortage situation.

As a member of the public, what information would you consider the most helpful when facing a drug or other health product shortage?

For medical devices, we believe the information should be provided by healthcare providers or by Health Canada and should include alternate products where possible. Notifying consumers when the resolution of the shortage is expected is good in the case of a complete shortage, however, if there is an alternate identified, this may not be as critical. Directions to the public should ensure that they do not create spike in demand or panic purchasing and hoarding.

As an industry member, a health care provider or a provincial or territorial government, what processes do you have in place for information-sharing, communication and transparency during an anticipated or actual shortage?

The communication from the currently regulated industry (manufacturer, importer and/or distributor) to healthcare is done with the immediate customer (to the supplier) and to Health Canada where required. The processes are documented within the quality system of the company.

The challenges we have seen are within the unregulated parts of the healthcare supply chain continuum where there are little to no requirements around quality systems. The communication systems vary in the ability to transfer information internally (or to their subsequent customers or patients) in a consistent manner. This is exacerbated in areas that also lack product traceability further challenging the ability to transfer communication and information to the appropriate parties. We recommend regulating the supply chain continuum for medical devices to a minimum standard of quality which would include third party service providers, and which would require all to:

- Establish and maintain a communication process for:
    - Recalls
    - Reportable events
    - Shortages
    - Signal reporting (to Health Canada)
- Establish and maintain traceability of medical devices sold, transferred, and repaired (to ensure the communication being sent is provided to the correct customers)

What are the biggest challenges you face in communication and transparency related to shortages?

Currently, the information flow seems to be one way as indicated in prior recommendations and sections (see Recommendation #2 , Section 2.1 and Section 2.2). This is also a challenge when requesting and receiving approvals for exceptional importation – where each federal and provincial agency has their own contacts and process for managing issues and approval.

In some cases, industry is not receiving future demand planning numbers from the healthcare settings which would help them avoid shortages due to expected surges. In addition, there is a difficulty in planning for a port or truck or train strike. These types of strikes that impact healthcare should be avoided as best possible and plans should be in place to resolve the resulting healthcare shortages that results in these cases.

Another signal that is not discussed but is impacting industry and creating shortages is the ongoing changes in the regulations at a national, provincial, and international level. Recommendation #3 and Recommendation #4 speak to this challenge and potential resolutions.

What is the most effective way for you to receive information on a drug or other health product shortage?

The answer to this question depends on the entity receiving the information and the context and details. Medtech Canada highly recommends that, with respect to medical devices shortages, the information throughout the supply chain be managed through the recommended database (Appendix #1, Recommendation #1 and Recommendation #2). We recommend that the information to the consumer be highly controlled to ensure that we avoid panic purchasing as noted in prior comments.

What type of information are you missing to respond to a shortage or shortage risk in a timely manner?

Industry is requesting improved communication around increase in demand and future planning from healthcare providers. As procedures increase and surgical backlogs are being resolved, it is vital that suppliers are advised in a timely and thorough manner to manage the potentials spike and ensure patients are treated. In addition, a standardized escalation process across facilities would assist suppliers in better prioritizing internally to support the various entities. When one facility indicates a product is critical and another facility does not, suppliers will be challenged to align on the escalation and prioritization of the shortage, causing a delay in response.

The above recommendations have also been identified in Recommendations #1 and Recommendation #2 earlier in this document.

In addition, as noted in the prior response, industry is also requesting a clear communicated pathway for industry to request alternate products (to those impacted by a shortages) for those that need to be brought in as an exceptional importation. The information on a process that would cover all impacted jurisdictions and preferably through one application portal would be highly effective and efficient. These

are further recommendations noted in Recommendation #3, Recommendation #4 and Recommendation #5.

Medtech Canada, in collaboration with those attending the Medical Devices Shortages Multi-Stakeholder Committee have been diligently working on a set of definitions that would apply across the supply chain and the intent is to standardize terms and classification of the communications used during a shortage. The examples that are currently being worked on can be found in Appendix #2 and further discussed under Recommendation #6.

Key area 2: Agile regulatory toolbox

In the consultation portion of this key area, an important aspect of our current complex Canadian regulatory framework is discussed:

- *federal regulations focus on the activities of market authorization holders*
- *provincial and territorial governments provide for health care and distribution of medicines to patients through the regulation of the practice of medicine and pharmacy*

Unlike drugs, medical devices have a larger regulatory burden in Canada. Both federally and provincially the regulations and requirements that apply to medical devices pose a challenge during regular day-to-day business, which creates a larger challenge during a shortage where time is of essence. Examples of these regulations are the Food and Drug Act, which is expected, however we also must meet electrical safety approvals (where each province has a different list of approved registrars), Quebec French language requirements (which impact devices more than drugs due to the federal exemption for French in the case of professional medical devices), provincial requirements around x-ray and other radiation emitting devices. In addition, the medical device industry was recently added to the Pest Management Regulatory Agency (PMRA) requirements (which we have escalated separately to PMRA and Health Canada).

We are seeing more regulations (outside of the Food and Drug Act) to which we are now responding, such as plastics labelling and PFAS. If these come into effect, they will further add a regulatory burden and time to our speed to react in cases of shortages and/or pandemic. Some of these have the potential unintended consequence of creating shortages (such as PFAS and PMRA).

As such, although within the Food and Drug Act we are seeing significant progress in creating an agile regulatory toolbox to support both shortages and regular day to day regulatory burden, this is not seen to-date in the other regulatory frameworks, which will undermine the aforementioned advancements within the Food and Drug Act.

Later in the consultation there is a key statement that we believe is critical in ensuring a successful implementation of a standardized system that will react appropriately to healthcare shortages:

"*To be effective, regulatory tools must keep pace with changes that affect the supply chain.*"

Based on the above comments within the consultation, below are more detailed recommendations on how this can be effectively implemented:

1. Regulatory Change Control Process

As per our prior comments within this section and as noted under Recommendation # 4, the regulatory tool needs to encompass not only the evolving industry landscape but also the evolving regulatory landscape such as the Food and Drug Act, Pest Management Regulatory Agency, French language requirements as well as all other applicable and additional federal and provincial regulatory requirements (imposed on industry) as amended from time to time. It's only through this ongoing change control process that we can ensure that the regulatory tools are keeping at the same pace as industry and with the regulatory framework itself, which is constantly evolving.

2. Parallel Exceptional Importation Submission Pathway

There is currently a regulatory application tool that is being co-developed called eSTAR – this tool is a portal where manufacturers that wish to apply for both USA and Canada approvals can do so within one portal.

We can leverage this approach and apply it to the issue of the diverging regulatory pathways previously discussed within this document. In the case where there is a confirmed national shortage, a manufacturer, importer or distributor (as well as the regulatory agencies impacted) may find it helpful to have one portal where they submit all required information that all affected agencies require in order to evaluate and quickly respond to a shortage situation (see Recommendation #5). This will allow for a parallel review and approval by both provincial and federal agencies and would also provide the manufacturer/importer/distributor the assurance that the final approval granted through this portal covers all their regulatory requirements both now and in future, should the device be one that remains on the market after the shortage is resolved and considering that the average lifespan of medical device equipment is 10 years.

In order for a tool to be successful, guidance and timelines for submission and approval would be required. An excellent example of this would be the timelines associated with a Special Access approval where Health Canada provides a timeline outlining their response to an emergency access request. This would need to consider the situation as an emergency so that the cumulative time of all the reviews would be short e.g. ,3 business days. This is of critical importance as once the approval is provided, industry will still need to react to any conditions, e.g. over-labelling, transportation and any terms and conditions to approval that may be provided, and then the transportation timelines may be lengthy.

It's also important to note that this tool can be expanded to be used internationally, similar to the eSTAR and may even support the current global initiatives around Pandemic Planning which is being coordinated through the WHO (https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf).

Questions for discussion:

What information or tools would better prepare you to prevent or mitigate the impacts of drug shortages? Why?

As indicated previously, the following recommendation would apply:

- Recommendation #1 - Establish a process to define and manage priority issues and signals
- Recommendation #2 - Centralized database
- Recommendation #3 - Holistic national and international regulatory agility
- Recommendation #5 - Parallel single review portal
- Recommendation #6 - Common definitions

What do you believe are the most frequent causes of shortages?

This question can only be answered by requesting both industry and healthcare to provide input. To-date most databases (such as the Drug Shortages Database and the Multistakeholder) have assumed the root cause to be industry, which has skewed the data. The multiple sources of shortages noted at the start of this response (which are only a portion), will have at any given time an impact depending on the issue of focus at the time. During COVID-19 for example, the root cause was spike in demand. Second was labour on all levels of supply chain from manufacturer, importer, distributor, transportation and even within the healthcare system as supplies needed to move within hospital networks, shared service organizations and within the hospital itself to the bedside. A third, still of impact today, is labour strikes across the supply chain as well as challenges and delays at ports of entry.

What actions are you taking to prevent these causes from leading to a shortage?

Industry has intensified that collection of information to gather as much demand management and inventory planning as possible. In addition, industry and procurement organizations have increased the number of alternate suppliers within the system (both finished products and/or raw materials).

Various alternatives for transportation have also been a necessary focus due to the increase in challenges around transportation of healthcare products.

What are the advantages and challenges to developing a list of drugs vulnerable to shortages? What can be done?

Please see the response noted previously in section 2.5 around the dangers of assuming a specific shortage will occur without a related confirmed signal – this is particularly more challenging for medical devices due the diverse nature and variety of devices in the Canadian medtech ecosystem.

Section 2.2 discusses an alternate stockpile – of raw materials and components – which would enable us to be better equipped for an unexpected shortage.

What other processes could you or your organization put in place to better prevent, detect and address the risks of a shortage for your products?

Industry has the strongest and most senior way of detecting, preventing, and addressing risks of shortages. The key area that is missing is receiving the signals not only from the industry suppliers but also from the remaining supply chain such as accurate demand management, pending labour issues from the supply chain, new regulations (and or regulations being implemented at a speed that industry is unable to meet), and potential endemic or pandemics. We recommend using the recommended database and process of signal detection discussed withing our initial recommendations to identify and escalate signals throughout the supply chain to the various players.

Key area 3: Greater supply chain visibility

This section of the consultation speaks to a perceived lack of information about the supply chain.

"A lack of key information about the supply chain creates challenges for developing proactive measures to prevent and mitigate a shortage. Unexpected changes in demand, difficulty in accessing raw materials and disruptions in supply from other countries present challenges for Canada's supply."

The key challenge is ensuring that the right communication with correct stakeholders flows across the supply chain. In addition, the engagements need to include industry as active participants into the visibility and engagement in all regulatory changes that may impact it. Recent events identified instances where regulatory changes have been made without proper industry consultation, creating a lack of visibility into new and evolving regulations and increasing the potential to unintended shortages.

Questions for discussion:

What are your biggest challenges when it comes to supply chain or inventory visibility?

- Poor visibility into demand management and planning from healthcare providers.
- Poor visibility into non-industry related signals such as labour disputes, regulatory changes, global socioeconomic challenges etc.
- Different shortage and product priorities from different facilities, provinces and territories which do not enable a focused response to shortages.

What solutions would support improvements in your industry with respect to supply chain visibility?

Industry recommendations:

1. Require basic Quality System around traceability throughout the Canadian supply chain.

We recommend that the full Canadian healthcare supply chain implements basic standardized quality systems around product traceability, communication (recalls, shortages, complaints) and vendor qualification.

Visibility is not the first step of the solution; by having visibility without having the basic quality system around vendor qualification or traceability one cannot start to resolve a potential or existing shortage as the information is fraught with errors due to the lack of standardized quality systems.

2. Regulate areas within healthcare supply chain that today lack regulatory oversight and that have impact on the visibility and traceability of healthcare products.

Even with the future proposed implementation of UDI barcoding on medical devices, only a small portion of the healthcare system will be required to have quality systems in place to support it: the regulated industry. None of the downstream facilities (healthcare facilities, third party service providers, retailers, long term care facilities, physician's offices) seem to have any regulatory requirements that require them to continue and implement a system that sustains the integrity of the UDI traceability of the devices within the Canadian healthcare systems. The basic quality system recommended would have processes for traceability, vendor qualification and communications (in case of recall, reportable events and shortages).

3. Ensure we have the full supply chain engaged in solutions.

In this section of the consultation there is a reference to parts of the supply chain, however in cases of shortages, and depending on the root cause, the entire supply chain should be part of the solution. This would include transportation, border services, unions and even representatives from the public that can provide a representative viewpoint. We should also ensure to include those that are located in remote areas as their needs and challenges may differ from those in major cities (for examples some products cannot be air-shipped to a remote location or there is no cold storage transportation available).

4. Improve and standardize further the current Quality Systems for MDEL holders without increasing the regulatory burden for internal suppliers.

Instead of adding additional regulatory burdens to international companies who sell their devices into a regulated and licenced medical device importer (MDEL holder), provide additional guidance around how to standardize and improve the MDEL quality systems, for example:

a. Require importers and other MDEL holders to hold quality agreements with their immediate vendors that depict responsibilities around shortage reporting, post market surveillance, recalls as well as minimum vendor qualifications and points of contact (similar to the GMP requirements)
b. Add additional details to the current MDEL renewal to include points of contact for suppliers that are listed on the MDEL that do not hold an MDEL themselves.s
c. Identify points of contact for each MDEL holder in cases of shortages so that the right facility is contacted in case of a shortage. In some cases, the importer has more information on a shortage as opposed to the manufacturer as it may be due to transportation. Contacting manufacturers directly in these instances leads to confusion and misunderstandings.

In this portion of the consultation – one of the actions noted is that an example of action would be *"setting and implementing standards for collecting and sharing data to promote a rapid response to shortages across Canada".* It is extremely important to note that proceeding with this stage of the process without ensuring first that the data is accurate would be the same as using an unvalidated software that does not have data integrity. The data collected would not be reliable. As such the first step should be to ensure the data is reliable by setting up and implementing these basic quality system standards end-to-end throughout the supply chain.

5. What concerns do you or your organization have when it comes to sharing information that would increase supply chain visibility with Health Canada or other supply chain partners?

Confidential business information should always be handled securely. There should be a clear alignment between Health Canada and industry as to what is considered business confidential.

6. What initiatives in your profession/sector are under development to improve supply chain or inventory visibility?

Medtech Canada, representing its members, participates in various committees and with provincial entities in order to provide industry's perspective and support around improving supply chain resiliency and reducing shortages. We support ongoing discussions and consultation and recommend increasing the participation of missing stakeholders such as:

- Other affected regulatory agencies (federal and provincial)
- Healthcare facilities
- Consumer group representatives
- Logistics and transportation

Key area 4: Enhanced response to supply and demand

This key area discusses the potential proven successes during shortages. It's important to note that these successes were effective only after the impacted devices were identified due to the specific signal (a specific pandemic for example). As such, the planning for robust stock of drugs and devices is not a realistic plan unless one knows well in advance that a pandemic or shortage is on the way, allowing for the identification and stockpiling of applicable impacted healthcare products.

One also needs to note that many medical devices and drugs expired and had to be thrown out during the pandemic, these included vaccines. The stockpiling of healthcare products needs to be done based on clean and accurate data obtained from the supply chain, married to clean, timely and clear signal detection as well as proactive relationships and agreements with industry to react to the signal and create these products.

Medtech Canada agrees that a more diverse marketplace is more resilient, however the diversity being sought is competing with the ever-increasing regulatory burden (both international and national). In time of shortages, the supply chain will naturally stream to the areas and countries where the regulatory burden is shorter and processes are simpler as all healthcare products have a shelf life and the longer companies wait for approval, the less positive impact the product will have (as some may expire before reaching the patient).

Questions for discussion:

When is it most useful to have safety stocks or extra supply in the supply chain?

Please see above comment in regard to the timing of the safety stock to improve accuracy of the response.

What kind of support do you need to be better prepared to react to a rapid change in demand?

Improve signal detection from all supply chain parties as noted previously in our response to this consultation.

What type of regulatory alignment would you see as beneficial to improve access to health products for people in Canada?

In our initial recommendations we have identified a few key areas of alignment:

Recommendation #3 - Wholistic National and international Regulatory Agility.

Recommendation #4 - Implement a "Regulatory Change Control" process within the government's Shortages unit.

Recommendation #5 - Parallel single review portal.

Recommendation #6 - Common Definitions.

In addition, in our response section for the Key Area 2: Agile Regulatory Toolbox , there is further feedback which aligns with the above recommendations.

How can we incentivize market diversity?

Advanced category management frameworks for procurement and contracting practices have enhanced the diversity of supply over the last few years and have built contingency and performance metrics into partnerships with industry. These practices should be supported as they also align with value for money principles and evaluation criteria beyond unit pricing. Ultimately, provinces and territories have governance over these practices and could work with hospital corporations and procurement organizations to increase uptake and adopt best practices.

Summary

On behalf of Medtech Canada and our member organizations, we thank you again for the opportunity to provide industry perspectives on the Consultation on improving access to drugs and other health products in Canada.

Our main recommendations center around the streamlining of the regulatory framework that impact our ability to bring devices to market both during regular market conditions as well as shortages, and in addition the need to improve the foundation of our supply chain so that when we do gather the data and

gain visibility – that it is "clean and objective data" that can be trusted and used to make decisions on shortage avoidance and/or mitigation.

Some of the key recommendations we have identified are:

- Centralized and objective database managed through a centralized and independent party.
- Requiring all Canadian supply chain to implement standard processes to ensure accuracy of data and traceability (to feed clean data into the database).
- Standardized definitions to reduce misinformation – both within Canada and internationally.
- Define and implement a holistic objective Signal Detection definition and process.
- Create a prioritization process that focuses on national shortages but where possible also assist with local shortages (that may also be considered signals).
- Centralize platform to review and approve exceptional importation that provides a parallel review platform for products coming into Canada to alleviate shortages and that provides industry with clear and holistic approvals.
- Work with international bodies to work on similar parallel approval solutions so that companies may do so for various countries at the same time, supporting our international and national obligations and humanitarian efforts.
- Ensure that government agencies, similar to industry, implement and/or enhance their change control process to ensure that as the regulatory framework changes in each country, this tool (the parallel review and approval for shortages) is updated to ensure that it maintains its holistic approach. This will be even more important where different countries differ in their requirements.

Medtech Canada welcomes any follow up questions and/or feedback in regard to this consultation and we look forward to the continuing involvement and participation in the various committees and working groups who are focused on resolving the shortages challenges we today face within the Canadian medtech ecosystem. For further information, please reach out to Mia Spiegelman, VP Regulatory Affairs, at mspiegelman@medtechcanada.org.

Appendix #1 – Centralized Database and Data collection:

Improve demand management by establishing a centralized database to which all stakeholders, including industry, have access.

The central database should have the following:

1. Simple process to ensure up to date contact information is available for all parties (those that are reporting shortages – whether a manufacturer/importer or procurement organization and those that should be notified of shortages). The system should be self-governing regarding updating of contact information to prevent the need for Health Canada to do so. The requirement would be that each entity should have a minimum of 2 contact personnel and perhaps an annual reminder to update/check the information.

2. Reported shortages from customers/consumers should indicate:

    a. Is the shortage existing or imminent?
    b. Product code(s) and descriptions
    c. Expected volume required in next month, 3 months and 6 months – it should indicate it by EA as a default
    d. Reason for shortage
        - Unexpected demand increase
        - Recall/faulty materials
        - Supplier reported shortages
        - Damages on site (for example, fire)
    e. Was a replacement product identified? Yes/No (this will help with urgency)
    f. If the replacement has been identified, is it:
        - Direct replacement
        - Similar to replacement
        - Limited replacement
    g. Has the buying group reached out to other provinces and has this shortage been mitigated? Yes/No

3. Reported shortages from suppliers
    a. Catalogue and product code
    b. Reason for shortage
        - Raw material – acute/chronic (acute would be one source and others are available and chronic would be a widespread shortage)
        - Recall
        - Spike in demand
        - Other

c. Expected shortage timelines (based on demand planning information to supplier from provinces – so this would not include unreported spikes in demand)
d. If the replacement has been identified, is it:
    - Direct replacement
    - Similar to replacement
    - Limited replacement
e. Is the supplier able to provide this replacement? Yes/No
f. Does this replacement require SAP or IO or neither?

Ideally, these shortages would be posted on a database that would help bridge communications between parties. At the same time this will feed data on the Health Canada engine that would identify ongoing shortages and chronic issues that may end up in the national database. The database described above would be self-sustaining otherwise.

Appendix #2 – Definitions

Having a common language and understanding of specific key words is it critical to reduce misinformation and understandings as it removes subjectivity and ensures that the issues being discussed are understood equally by all parties. The Multi-stakeholder committee has been working on a predefined description of terminologies. Below is an example of those that have been submitted as an example to the committee. As this work is in progress We expect the below to change as well as further definitions are expected to come out of this joint collaboration work between Industry, Provinces and Territories and Health Canada.

Name	Description	Patient Impact?	Vendor/Customer Relationship
Chronic Shortage	Ongoing Lack of ability to fulfill supply needs for products/solutions which is affecting actual health care delivery AND is based on prescribed original demand	Yes	Existing
Acute Shortage	Short term Lack of ability to fulfill supply needs for products/solutions which is affecting actual health care delivery AND is based on prescribed original demand	Yes	Existing
Increase in actual demand	Unexpected/unusual short term (1-2 week) increase in health care delivery demand which is DIRECTLY related to immediate health care delivery needs (i.e., for immediate patient use and not for stocking up supply in hospital)	Yes	Existing
Increase in projected demand	Unexpected/Un forecasted increase in demand to suppliers that is requested in order to accommodate new adjusted inventory management approach or unplanned volume requirements in the health care system (i.e., expanded procedural volume, additional beds, etc)	No	Existing
Limited allocation	Supplier-managed short term (1-3months) allocation of limited supply in order to fairly meet customer needs with the intent of meeting immediate patient needs. Patients are not impacted and there are no cancelled procedures.	No	Existing
New Demand	New product or new supplier/vendor relationship where vendor is requested to supply product to customer where no prior demand was identified	Yes and No	New